



January 7, 2025

DRGEM Corporation  
% Jongseon Park  
Regulatory Affairs | Engineer  
7F, E-B/D Gwangmyeong Techno-Park, 60Haan-ro,  
GwangMyeong-si, Gyeonggi 14322  
SOUTH KOREA

Re: K242019

Trade/Device Name: GXR-series diagnostic x-ray system  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary X-Ray System  
Regulatory Class: Class II  
Product Code: KPR, MQB  
Dated: July 10, 2024  
Received: December 3, 2024

Dear Jongseon Park:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Lu Jiang" is positioned over a large, light blue, semi-transparent watermark of the letters "FDA".

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiologic Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K242019

Device Name

GXR-Series Diagnostic X-Ray System

Indications for Use (Describe)

The GXR-Series Diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnostic by using X-rays.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

**K242019**

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

### **I. SUBMITTER [21 CFR 807.92(a) (1)]**

DRGEM Corporation  
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Contact Person: Mr. Jongseon PARK, Engineer | Regulatory Affairs  
Date Prepared: June 15, 2024

### **II. PROPOSED DEVICE INFORMATION [21 CFR 807.92(a) (2)]**

Product Name: GXR-Series Diagnostic X-Ray System  
Common Name: Stationary X-Ray System  
Classification Name: Stationary x-ray system  
Product Code: KPR  
Regulation Number: 892.1680  
Associated Product Code: MQB  
Regulatory Class: II

Available Device Models : (Models: GXR32S, GXR-40S, GXR-52S, GXR-68S, GXR-82S, GXR-C32S, GXR-C40S, GXR-C52S, GXR-U32S, GXR-U40S, GXR-32SD, GXR-40SD, GXR-52SD, GXR-68SD, GXR-82SD, GXR-C32SD, GXR-C40SD, GXR-C52SD, GXR-U32SD, GXR-U40SD, FDR Clinica FGXR-32S, FDR Clinica FGXR-40S, FDR Clinica FGXR-52S, FDR Clinica FGXR-68S, FDR Clinica FGXR-82S, FDR Clinica FGXR-C32S, FDR Clinica FGXR-C40S, FDR Clinica FGXR-C52S, FDR Clinica FGXR-U32S, FDR Clinica FGXR-U40S)

### **III. PREDICATE DEVICES INFORMATION [21 CFR 807.92(a) (3)]**

Product Name: GXR-series Diagnostic X-Ray System, (Models GXR-S, GXR-SD series)  
Common Name: Stationary X-Ray System  
Classification Name: Stationary x-ray system  
510(k) Number: K202572  
Product Code: KPR  
Regulation Number: 892.1680  
Regulatory Class: II

#### **IV. DEVICE DESCRIPTION [21 CFR 807.92(a) (4)]**

##### **• Device Features:**

##### **• GXR-S/CS/US ‘Analog Diagnostic X-ray System’**

“GXR-S/CS/US” system provides excellent performance and stable operation while state-of-the-art image quality. The “GXR-S/CS/US” Series High Voltage X-Ray Generator features excellent accuracy, reproducibility, and long-term stability.

Automatic Calibration function of the generator will minimize calibration time and set correct calibration value. Also the control console of “GXR”, “GXR-C”, “GXR-U” series offers graphic waveform and data of x-ray exposure. So, it is not needed to perform the manual calibration procedure with measurement equipment. Naturally, the generator supports Automatic, Semi-auto and Manual Calibration functions. Adaptable calibration function keeps up long-term stability and accuracy by trimming calibration data whenever x-ray exposed.

The “GXR-C” Series High Voltage X-Ray Generator features excellent accuracy, reproducibility and long-term stability with capacitor assisted general line power supply. Only 3kVA line power capacity is enough for x-ray generation up to 40kW, and “GXR-C” series provides minimum 100mAs output at maximum output rating without mA sliding down.

Also, maximum interval for full charging is 10 seconds after maximum output x-ray generation. Only 900VA line power capacity is enough for the battery charging, and “GXR-U” series provides same output rating and performances of line-powered generators. The operator control console is designed in two types to be simple and user-friendly. The first type features a large graphic LCD panel display and a soft membrane switch to allow easy selection or change of X-ray parameters. The second type can be easily operated using the Touch function through a large graphic LCD panel display and intuitive GUI configuration. Remote Diagnosis Software can make report about information of system, user, service and error by the USB connection between PC and control console, and transfer report to manufacturer via internet. So this function enables fast and accurate diagnosis on problems and saves service cost and system downtime. The APR (Anatomical Programming) and the optional AEC (Automatic Exposure Control) features give you controlled exposure factors, automatically optimized for the radiological study selected.

##### **• GXR-SD/CSD/USD ‘Digital Diagnostic X-ray System’**

“GXR-SD/CSD/USD” system provides excellent performance and stable operation while state-of-the-art image quality.

The “GXR”, “GXR-C”, “GXR-U” Series High Voltage X-Ray Generator features excellent accuracy, reproducibility and long-term stability.

Automatic Calibration function of the generator will minimize calibration time and set correct calibration value. Also the control console of “GXR”, “GXR-C”, “GXR-U” series offers graphic waveform and data of x-ray exposure. So, it is not needed to perform the manual calibration procedure with measurement equipment. Naturally, the generator supports Automatic, Semi-auto and Manual Calibration functions.

Adaptable calibration function keeps up long-term stability and accuracy by trimming calibration data whenever x-ray exposed.

The “GXR-C” Series High Voltage X-Ray Generator features excellent accuracy, reproducibility and long-term stability with capacitor assisted general line power supply. Only 3kVA line power capacity is enough for x-ray generation up to 40kW, and “GXR-C” series provides minimum 100mAs output at maximum output rating without mA sliding down.

Also, maximum interval for full charging is 10 seconds after maximum output x-ray generation.

Only 900VA line power capacity is enough for the battery charging, and “GXR-U” series provides same output rating and performances of line-powered generators.

Remote Diagnosis Software can make report about information of system, user, service and error by transfer report to manufacturer via internet. So this function enables fast and accurate diagnosis on problems and saves service cost and system downtime.

The APR (Anatomical Programming) and the optional AEC (Automatic Exposure Control) features give you controlled exposure factors, automatically optimized for the radiological study selected.

“GXR-SD/CSD/USD” provides state-of-the-art image quality; image processing and user interface; making the system easy to use.

“GXR-SD/CSD/USD” incorporates the digital flat panel detector technology.

Direct radiography via flat panel detector improves your workflow, exam speed and comfort with efficiency. Digital flat panel detector provides excellent spatial resolution, MTF, DQE and stability based on fine pixel pitch. Selection of an anatomical study on the imaging software automatically sets up the x-ray generator's pre-programmed exposure technique setting and post image processing for selected study. Also, high resolution grid supplies excellent image quality.

A high performance imaging workstation and “RADMAX” software serves you a convenient interface and easy operation. Anatomical view-based digital image processing automatically optimizes and enhances the quality of the captured images. Automatic image storage and print with DICOM 3.0 networking capability increases exam throughput and decreases examination time. Remote diagnosis function enables fast and accurate diagnosis on problems and saves service cost and system downtime.

#### • **Device Identification:**

The GXR Series Diagnostic X-ray System consists of a combination of an x-ray generator, and associated equipment such as tube stand, patient table, and, digital imaging system.

#### • **Device Characteristics:**

##### **Software**

The subject device ‘GXR-Series Diagnostic X-ray System’ use software (including firmware).

[GXR-S, CS, US ‘Analog Diagnostic X-ray System’]

Its S/W (X-CON) can perform system control such as the collimation size, filter selection, Control of Generator.

[GXR-SD, CSD, USD ‘Digital Diagnostic X-ray System’]

Its S/W (RADMAX) can perform processing the radiological image acquired from Solid State X-ray Imaging Device.

Both software being used is identical to the predicate device “GXR-series Diagnostic X-ray System”, and its LOC (Level of Concern) is 'Moderate'.

Accordingly, this software (X-CON) is based on predicate device ‘GXR-S series Diagnostic system.

### **Software Level Determination**

(Moderate Level of Concern)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets all images and information being displayed and printed.

#### **• Environment of Use:**

This “GXR-series Diagnostic X-ray System” is for use by medical professional Facility. To prevent excess radiation exposure to patient and operator from either primary or secondary radiation, this “GXR-Series Diagnostic X-ray System” must be operated and serviced by trained personnel who are familiar with the safety precautions required.

#### **• Brief Written Description of the Device:**

The operating principles are as follows.

The irradiation conditions are 40 to 125 (150) kVp at the photographing site, and the tube current is 10 to 400 (500) mA. When X-rays generated under X-ray irradiation conditions enter the X-ray Film or Flat Panel detector, the film or flat panel detector detects X-rays incident through the incident surface during X-ray irradiation, and finally generates a radiographic image when X-ray irradiation is completed (in case of Digital Diagnostic X-ray System, After Image processing, Digital Image for Diagnosis has been generated).

### **V. INDICATION FOR USE [21 CFR 807.92(a) (5)]**

The GXR-Series Diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnostic by using X-rays.

### **VI. TECHNOLOGICAL CHARACTERISTICS [21 CFR 807.92(a) (6)]**

The Subject device ‘GXR-Series Diagnostic X-ray System’ (Model: GXR-S, GXR-SD series) is based on the Predicate Device (GXR-series, K202572) including the system control, Indication for use and mechanical design.

The differences between the subject device and the predicate device have been thoroughly tested and verified for safety and effectiveness by an accredited Safety and EMC testing laboratory.

This 510(k) submission describes some modifications to the previously cleared predicate devices the ‘GXR-SD Series’ (K202572). The changes to the predicate ‘GXR-SD series’ (K202572) include:



### **System Imaging Software 'RADMAX'**

- **Graphical user interface (GUI):** GUI of system software updated in order to improve the look and feel of user interface for better visibility & faster workflow.
- **Image Processing Module added (Module 4):** We conducted performance verification of Flat Panel detectors compared to existing image processing modules. Verification and Validation testing concluded no impact on safety and effectiveness.

### **Component Change**

#### **·10x12 inch Wireless Flat Panel detectors have been added**

- Luna1012X manufactured by IRAY Technology, FDA Cleared K221345

#### **·14x17 inch Wireless Flat Panel detectors have been added**

- Mars1417X manufactured by IRAY Technology, FDA Cleared K210316
- A1417MCW manufactured by H&abyz Co., Ltd., FDA Cleared K223930
- F1417MCW manufactured by H&abyz Co., Ltd., FDA Cleared K223930

#### **·17x17 inch Wireless Flat Panel detectors have been added**

- Mars1717X manufactured by IRAY Technology, FDA Cleared K210314
- A1717MCW manufactured by H&abyz Co., Ltd., FDA Cleared K223930

#### **·Patient Table option has been added**

- PBT-6 (Deluxe) option manufactured by DRGEM

#### **·Wall Bucky stand option has been added**

- WBS (Manual Plus) option manufactured by DRGEM
- WBS-TA (Actuator) option manufactured by DRGEM
- WBS-TA (Deluxe) option manufactured by DRGEM

#### **·Tube Stand option has been added**

- TS-CSP (15inch LCD Panel) option manufactured by DRGEM

#### **·Tube Housing Assembly models have been added**

- RTM90HS Tube Housing Assembly option manufactured by IAE
- RTM101HS Tube Housing Assembly option manufactured by IAE
- RTC600HS Tube Housing Assembly option manufactured by IAE
- UH-6FC-31E Tube Housing Assembly option manufactured by Fujifilm

#### **·GXR-Series Diagnostic X-ray System's 'Variant models' have been added**

- : Variant models (FDR Clinica FGXR-S, CS, US) of Subject Device have been added. These models are manufactured for OEM Contractor (Fujifilm Corporation).  
Difference between predicate device (GXR-S, CS, US 'Analog Diagnostic X-ray System') and OEM Model (FDR Clinica FGXR-S, CS, US) has only label, exterior color, model name.

## Substantial Equivalence Comparison

### VII.SUBSTANTIAL EQUIVALENCE [21 CFR 807.92(b)]

#### Substantial Equivalence Comparison Table

| Item               | Subject Device                                                                                                                          |                        | Predicate Device                                                                                                                                                                                                                          |           | Impact of Differences                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Name        | GXR-Series Diagnostic X-ray System                                                                                                      |                        | GXR-Series Diagnostic X-ray System                                                                                                                                                                                                        |           | Same                                                                                                                                                                                                                                                                                                                                                                                   |
| 510(k) number      | K242019                                                                                                                                 |                        | K202572                                                                                                                                                                                                                                   |           | -                                                                                                                                                                                                                                                                                                                                                                                      |
| Indication for use | The GXR-Series Diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnostic by using X-rays. |                        | GXR-Series Diagnostic X-ray System is a stationary X-ray imaging system, for the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. This device is not intended for mammography or bone density applications. |           | Both devices are fundamentally intended to acquire anatomical images of patients for medical diagnostic purposes.<br><br>This means they essentially share the same indication for use. Some contents mentioned in the predicate device's Indication for use are described in the IFU(operation Manual)_Contraindication section of the subject device.                                |
| Manufacturer       | DRGEM Corporation                                                                                                                       |                        | DRGEM Corporation                                                                                                                                                                                                                         |           | Same                                                                                                                                                                                                                                                                                                                                                                                   |
| Model Name         | Analog Diagnostic X-ray System                                                                                                          |                        | Digital Diagnostic X-ray System                                                                                                                                                                                                           |           | Variant models (FDR Clinica FGXR-S, CS, US) of Subject Device have been added. These models are manufactured for OEM Contractor (Fujifilm Corporation). Difference between predicate device (GXR-S, CS, US 'Analog Diagnostic X-ray System') and OEM Model (FDR Clinica FGXR-S, CS, US) has only label, exterior color. All Specification is same as predicate device (GXR-S, CS, US). |
|                    | DRGEM                                                                                                                                   | Fujifilm               | DRGEM                                                                                                                                                                                                                                     | DRGEM     |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-32S                                                                                                                                | ·FDR Clinica FGXR-32S  | ·GXR-32SD                                                                                                                                                                                                                                 | ·GXR-32S  |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-40S                                                                                                                                | ·FDR Clinica FGXR-40S  | ·GXR-40SD                                                                                                                                                                                                                                 | ·GXR-40S  |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-52S                                                                                                                                | ·FDR Clinica FGXR-52S  | ·GXR-52SD                                                                                                                                                                                                                                 | ·GXR-52S  |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-68S                                                                                                                                | ·FDR Clinica FGXR-68S  | ·GXR-68SD                                                                                                                                                                                                                                 | ·GXR-68S  |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-82S                                                                                                                                | ·FDR Clinica FGXR-82S  | ·GXR-82SD                                                                                                                                                                                                                                 | ·GXR-82S  |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-C32S                                                                                                                               | ·FDR Clinica FGXR-C32S | ·GXR-C32SD                                                                                                                                                                                                                                | ·GXR-C32S |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-C40S                                                                                                                               | ·FDR Clinica FGXR-C40S | ·GXR-C40SD                                                                                                                                                                                                                                | ·GXR-C40S |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-C52S                                                                                                                               | ·FDR Clinica FGXR-C52S | ·GXR-C52SD                                                                                                                                                                                                                                | ·GXR-C52S |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-U32S                                                                                                                               | ·FDR Clinica FGXR-U32S | ·GXR-U32SD                                                                                                                                                                                                                                | ·GXR-U32S |                                                                                                                                                                                                                                                                                                                                                                                        |
|                    | ·GXR-U40S                                                                                                                               | ·FDR Clinica FGXR-U40S | ·GXR-U40SD                                                                                                                                                                                                                                | ·GXR-U40S |                                                                                                                                                                                                                                                                                                                                                                                        |

| 1. High Frequency X- ray Generator                                         |                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Output Power Rating (kW)                                                   | 32kW, 40kW, 52kW, 68kW, 82kW                                                                                                                                                                                                                                                                                                                                                | 32kW, 40kW, 52kW, 68kW, 82kW                                                                                                                                                                                                                                                                                                             | same                                                                                                                                                                                                                                                                                                                                                                                                               |
| Generator models (manufactured by DRGEM)                                   | ·GXR-32<br>·GXR-40<br>·GXR-52<br>·GXR-68<br>·GXR-82<br>·GXR-C32<br>·GXR-C40<br>·GXR-C52<br>·GXR-U32<br>·GXR-U40                                                                                                                                                                                                                                                             | ·GXR-32<br>·GXR-40<br>·GXR-52<br>·GXR-68<br>·GXR-82<br>·GXR-C32<br>·GXR-C40<br>·GXR-C52<br>·GXR-U32<br>·GXR-U40                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Line voltage                                                               | 220~230VAC<br>380/400/480VAC                                                                                                                                                                                                                                                                                                                                                | 220~230VAC<br>380/400/480VAC                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2. Solid State X-ray Imaging Device (Digital Diagnostic X-ray System Only) |                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Flat panel Detector                                                        | ·PaxScan4343R v3 / VAREX<br>·PaxScan4343RC / VAREX<br>·PaxScan4336W v4 / VAREX<br>·4343W (Basic) / VAREX<br>·XRpad2 3025 HWC-M / VAREX<br>·XRpad2 4343 HWC-M / VAREX<br>·XRpad2 4336 HWC-M / VAREX<br>·Mano4343T / IRAY<br>·Mano4343X / IRAY<br>·Mano4336W / IRAY<br>·Mano4343W / IRAY<br>·Mars1417X / IRAY<br>·Mars1717X / IRAY<br>·Luna1012X / IRAY<br>·A1417MCW / H&abyz | ·PaxScan4343R v3 / VAREX<br>·PaxScan4343RC / VAREX<br>·PaxScan4336W v4 / VAREX<br>·4343W / VAREX<br>·XRpad2 3025 HWC-M / VAREX<br>·XRpad2 4343 HWC-M / VAREX<br>·XRpad2 4336 HWC-M / VAREX<br>·Mano4343T / IRAY<br>·Mano4343X / IRAY<br>·Mano4336W / IRAY<br>·Mano4343W / IRAY<br>·VIVIX-S1417N / VIEWWORKS<br>·VIVIX-S1717N / VIEWWORKS | Additional Solid State X-ray Image detectors from the predicate can be used with the system. The system has been tested and there is “No negative impact on safety or effectiveness”.<br>And also, All modified flat panel detector have been verified according to “SSXI non-clinical performance data”<br>There is no new potential or increased safety risks concerning were raised because of this difference. |

|                     |                                                                                      |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
|---------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
|                     | ·A1717MCW / H&abyz<br>·F1417MCW / H&abyz                                             |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
| 3. Patient table    |                                                                                      |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
| Configuration model | ·PBT-4 (Motorized)<br>·PBT-6 (Motorized)<br>·PBT-6 (Deluxe)                          |                                                                                                                                                                               | ·PBT-4 (Motorized)<br>·PBT-6 (Motorized)<br>·PBT-1<br>·PDT-1                                            | Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference |                                                                                                                                                 |
|                     | Table Top                                                                            | Longitudinal                                                                                                                                                                  |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | 1,100(±550)mm ±10mm<br>840(±420)mm ±10mm<br>640(±320)mm ±10mm                                                                                   |
|                     |                                                                                      | Transverse (Latera)                                                                                                                                                           |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | 350(±150)mm ±10mm                                                                                                                               |
|                     |                                                                                      | Vertical                                                                                                                                                                      |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | Travel                                                                                                                                          |
|                     | Speed                                                                                |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | 13~19mm/sec±10% (Full load to no load)                                                                                                          |
|                     | Operating                                                                            |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | Motorized movement by foot/Hand grip Switch Linear Actuator                                                                                     |
|                     | Bucky                                                                                | Mechanical                                                                                                                                                                    |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | ·740mm(±10)mm with standard tray<br>·500mm(±10)mm with rotating tray                                                                            |
|                     |                                                                                      | Table Tracking                                                                                                                                                                |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | ·710mm(±10)mm with standard tray (automatically move only)                                                                                      |
|                     | ·PBT-1<br>·PDT-1                                                                     |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
|                     | 4. Wall Bucky stand                                                                  |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
| Configuration model | ·WBS (Manual)<br>·WBS-TM (Manual)<br>·WBS (Manual Plus)                              |                                                                                                                                                                               | ·WBS (Manual)<br>·WBS-TM (Manual)<br>·WBS (Motorized)<br><br>·WBS-TM (Motorized)<br>·WBS-TA (Motorized) | Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference |                                                                                                                                                 |
|                     | Cassette stroke                                                                      | 1,220mm (300~1,520mm from floor to Bucky center) ± 10mm<br>1,390mm (300~1,690mm from floor to Bucky center) ± 10mm<br>1,640mm (300~1,940mm from floor to Bucky center) ± 10mm |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
|                     |                                                                                      | Electrical Rating                                                                                                                                                             |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | 100-240VAC, 160VA, 50/60Hz                                                                                                                      |
|                     |                                                                                      | Dimension/ Weight                                                                                                                                                             |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | 1,749(H) x 659(W) x 445(D) mm / 113kg(249lbs)<br>1,919(H) x 659(W) x 445(D) mm / 116kg(255lbs)<br>2,169(H) x 659(W) x 445(D) mm / 120kg(264lbs) |
|                     | ·WBS (Motorized)<br>·WBS-TM (Motorized)<br>·WBS-TA (Motorized)<br>·WBS-TA (Actuator) |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                 |
|                     | Cassette stroke                                                                      |                                                                                                                                                                               |                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                | 1,526mm (283~1,809mm from floor to Bucky center)±10mm                                                                                           |

|                                |                                                        |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|--------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
|                                |                                                        | 1,526mm (450~1,976mm from floor to Bucky surface)±10mm                                                              |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | Tilting Range                                          | -20° ~ 90                                                                                                           |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | Tilting Speed                                          | Up                                                                                                                  | 8.2°/s                                       |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                |                                                        | down                                                                                                                | 5.1°/s                                       |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | WBS-TA (Deluxe)                                        |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | Cassette stroke                                        | 1,566mm (283~1,849mm from floor to Bucky center)±10mm<br><br>1,566mm (591~2,157mm from floor to Bucky surface)±10mm |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | Tilting Range                                          | -20° ~ 90                                                                                                           |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | Tilting Speed                                          | Up                                                                                                                  | 8.2°/s                                       |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                |                                                        | down                                                                                                                | 5.1°/s                                       |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
|                                | Vertical Speed                                         | Normal                                                                                                              | 6.2 cm/s ± 15% (Up),<br>5.6cm/s ± 15% (Down) |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
| Fast                           |                                                        | 12.1cm/s ± 15% (Up),<br>11.8cm/s ± 15% (Down)                                                                       |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
| 5. Tube stand                  |                                                        |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
| Configuration model            | ·TS-FM6 (Motorized)                                    |                                                                                                                     |                                              | ·TS-FM6 (Motorized) | Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference |                                                 |
|                                | ·TS-FC6 (Motorized)                                    |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FC6 (Motorized)                             |
|                                | ·TS-FC4 (Motorized)                                    |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FC4 (Motorized)                             |
|                                | ·TS-FC2 (Motorized)                                    |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FC2 (Motorized)                             |
|                                | ·TS-FM6 (Manual)                                       |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FM6 (Manual)                                |
|                                | ·TS-FC6 (Manual)                                       |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FC6 (Manual)                                |
|                                | ·TS-FC4 (Manual)                                       |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FC4 (Manual)                                |
|                                | ·TS-FC2 (Manual)                                       |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-FC2 (Manual)                                |
|                                | ·TS-CSA (Manual, Motorized)                            |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-CSA (Manual, Motorized)                     |
|                                | ·TS-CSP (Manual, Motorized) / (7inch,15inch LCD panel) |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-CSP (Manual, Motorized) / (7inch LCD panel) |
|                                | ·TS-CSE (Manual)                                       |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·TS-CSE (Manual)                                |
|                                | Tube Rotation Angle                                    | ±135° , ±180°                                                                                                       |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ±135° , ±180°                                   |
| 6. X-ray tube housing Assembly |                                                        |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                |                                                 |
| Configuration model            | ·E7239X                                                |                                                                                                                     |                                              | ·E7239X             | Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference |                                                 |
|                                | ·DXT-8M                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·DXT-8M                                         |
|                                | ·E7242X                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·E7242X                                         |
|                                | ·DXT-11M                                               |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·DXT-11M                                        |
|                                | ·E7843X                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·E7843X                                         |
|                                | ·DXT-10M                                               |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·DXT-10M                                        |
|                                | ·E7876X                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·E7876X                                         |
|                                | ·E7884X                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·E7884X                                         |
|                                | ·DXT-12M                                               |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·DXT-12M                                        |
|                                | ·E7252X                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·E7252X                                         |
|                                | ·DXT-14U                                               |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·DXT-14U                                        |
|                                | ·RAD-14                                                |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·RAD-14                                         |
|                                | ·DXT-15U                                               |                                                                                                                     |                                              |                     |                                                                                                                                                                                                                                                                                                                                                                                                | ·DXT-15U                                        |

|                                                                        |                                                                                                                                                                                                          |                                                                                                                     |                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                        | <div>·RAD-21</div> <div>·RAD-60</div> <div>·RAD-92</div> <div>·E7255FX</div> <div>·E7254FX</div> <div>·E7869X</div> <div>·RTM90HS</div> <div>·RTM101HS</div> <div>·RTC600HS</div> <div>·UH-6FC-31E</div> | <div>·RAD-21</div> <div>·RAD-60</div> <div>·RAD-92</div> <div>·E7255FX</div> <div>·E7254FX</div> <div>·E7869X</div> |                                                                                                                                                                                                                                                                                              |
| Max. kV                                                                | 125kV, 150kV                                                                                                                                                                                             | 125kV, 150kV                                                                                                        |                                                                                                                                                                                                                                                                                              |
| 7. Collimator (Beam Limiting Device)                                   |                                                                                                                                                                                                          |                                                                                                                     |                                                                                                                                                                                                                                                                                              |
| Configuration model                                                    | <div>·R108</div> <div>·DXC-RML</div> <div>·R302MLP/A</div>                                                                                                                                               | <div>·R108</div> <div>·DXC-RML, DXC-RMH</div> <div>·R302A, R302MLP/A, R302MFMLP/A</div> <div>·MCR</div>             | Yes, there is a difference. Collimator Configuration Models have been partially deleted based on predicate device. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference |
| Lamp Type                                                              | LED lamp<br>(Over 160LUX at 100cm SID)                                                                                                                                                                   | LED and Halogen lamp<br>(Over 160LUX at 100cm SID)                                                                  |                                                                                                                                                                                                                                                                                              |
| Electrical Rating                                                      | 3VDC (1.5 V Battery x 4ea), 3mA                                                                                                                                                                          |                                                                                                                     |                                                                                                                                                                                                                                                                                              |
| 8. Image Processing and Storage (Digital Diagnostic X-ray System Only) |                                                                                                                                                                                                          |                                                                                                                     |                                                                                                                                                                                                                                                                                              |
| Configuration model                                                    | RADMAX                                                                                                                                                                                                   | RADMAX                                                                                                              | same                                                                                                                                                                                                                                                                                         |
| FDA Cleared                                                            | --                                                                                                                                                                                                       | K182537                                                                                                             | -                                                                                                                                                                                                                                                                                            |
| Software Version                                                       | RADMAX 1.02 V                                                                                                                                                                                            | RADMAX 1.01 V                                                                                                       | - see below difference                                                                                                                                                                                                                                                                       |
| Horizontal Flip                                                        | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Vertical Flip                                                          | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Rotate CW/CCW                                                          | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Text Annotation                                                        | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Ruler: Distance too                                                    | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Angle measurement tool                                                 | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Zoom                                                                   | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Magnify                                                                | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Image panning                                                          | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Auto fitting to window size                                            | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Image crop/cut                                                         | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Image Copy                                                             | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Recover the original image                                             | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |
| Window level                                                           | Yes                                                                                                                                                                                                      | Yes                                                                                                                 | same                                                                                                                                                                                                                                                                                         |

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CD Burning              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                 |
| DICOM Print             | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | same                                                                                                                                                                                                                                                                                                                                                                            |
| Image Stitching         | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | same                                                                                                                                                                                                                                                                                                                                                                            |
| Image Processing Module | <p>· MODULE 1<br/>Edge Enhancement: 0 ~ 50<br/>Contrast Factor : 1 ~ 200<br/>Image Frequency : 0 ~ 20<br/>Image Latitude : -10 ~ 10<br/>Sharpness : 0 ~ 100</p> <p>· MODULE 2<br/>Histogram Optimization : -100 ~ 100<br/>Skin line Weight : -100 ~ 100<br/>Latitude Compression : -100 ~ 100<br/>Contrast Enhancement : -100 ~ 100<br/>Edge Enhancement : -100 ~ 100<br/>Noise Suppression : -100 ~ 100<br/>Gamma : -20 ~ 20</p> <p>· MODULE 3<br/>Global Brightness : -100 ~ 100<br/>Global Contrast : -100 ~ 100<br/>Latitude Compression : -100 ~ 100<br/>S-Structure Enhancement : -100 ~ 100<br/>Noise Suppression : -100 ~ 100<br/>Gamma : -20 ~ 20</p> <p>· MODULE 4<br/>Global Contrast : -30 ~ 30<br/>Global Brightness : -20 ~ 20<br/>Local Contrast : 0 ~ 20<br/>Small Enhancement : 0 ~ 20<br/>Latitude Reduction : -20 ~ 20<br/>Noise Suppression : 0 ~ 20<br/>Gamma : -20 ~ 20</p> | <p>· MODULE 1<br/>Edge Enhancement: 0 ~ 50<br/>Contrast Factor : 1 ~ 200<br/>Image Frequency : 0 ~ 20<br/>Image Latitude : -10 ~ 10<br/>Sharpness : 0 ~ 100</p> <p>· MODULE 2<br/>Histogram Optimization : -100 ~ 100<br/>Skin line Weight : -100 ~ 100<br/>Latitude Compression : -100 ~ 100<br/>Contrast Enhancement : -100 ~ 100<br/>Edge Enhancement : -100 ~ 100<br/>Noise Suppression : -100 ~ 100<br/>Gamma : -20 ~ 20</p> <p>· MODULE 3<br/>Global Brightness : -100 ~ 100<br/>Global Contrast : -100 ~ 100<br/>Latitude Compression : -100 ~ 100<br/>S-Structure Enhancement : -100 ~ 100<br/>Noise Suppression : -100 ~ 100<br/>Gamma : -20 ~ 20</p> | <p>Yes, there is a difference. Models have been conducted Verification activity. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is "No negative impact on safety or effectiveness" and there are no new potential or increased safety risks concerning this difference</p> |

# VIII. SUMMARY OF NON-CLINICAL Data [21 CFR 807.92(b) (1)]

## Nonclinical Testing:

The GXR-Series Diagnostic X-Ray System, has been assessed and tested and has passed predetermined testing criteria. The Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by the subject device and followed the process documented in the System Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

| Std #                   | Safety/EMC Standards Description                                                                                                                                                                                        | FDA Rec. Standard # |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| IEC 60601-1-3           | Medical electrical equipment<br>Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment                                                                                                   | 12-336              |
| IEC 60601-1-6           | IEC 60601-1-6 Edition 3.1 2013-10<br>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability                                          | 5-132               |
| IEC 60601-2-28          | IEC 60601-2-28<br>Medical electrical equipment Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis                                                | 12-309              |
| IEC 60601-2-54          | IEC 60601-2-54<br>Medical electrical equipment<br>Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy                                      | 12-348              |
| IEC 60601-1-2 (EMC)     | IEC 60601-1-2 Edition 4.0 2014-02. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances Requirements and tests. | 19-36               |
| IEC 62304:2006          | IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION<br>Medical device software - Software life cycle processes                                                                                                           | 13-79               |
| IEC 60601-1             | Medical electrical equipment, Part 1: General requirements for basic safety and essential performance                                                                                                                   | 19-46               |
| ISO 14971:2019          | ISO 14971:2019 Third Edition, Medical devices - Applications of risk management to medical devices.                                                                                                                     | 5-125               |
| ISO 15223-1             | ISO 15223-1 Fourth Edition 2021-07, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.                                          | 5-134               |
| IEC 62366-1             | 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices                                                                                      | 5-129               |
| TR 60601-4-2            | TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems            | 19-19               |
| NEMA PS 3.1-3.20 (2022) | Digital Imaging and Communications in Medicine (DICOM) Set                                                                                                                                                              | 12-349              |
| ISO IEC10918-1          | ISO IEC10918-1 First edition 1994-02-15 Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including: Technical Corrigendum 1 (2005)]                | 12-261              |



|              |                                                                                                                                                                                                                     |        |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| IEC 62494-1  | IEC 62494-1 Edition 1.0 (2008-08) Medical electrical equipment- Exposure index of digital X-ray imaging systems - part 1: Definitions and requirements for general radiography                                      | 12-215 |
| FDA Guidance | Pediatric Information for X-ray Imaging Device Premarket Notifications dated November 28, 2017                                                                                                                      |        |
| FDA Guidance | Format for Traditional and Abbreviated 510(k)s, Guidance for Industry and Food and Drug Administration Staff, Document issued on September 13, 2019.                                                                |        |
| FDA Guidance | Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices dated September 1, 2016                                                                                                                |        |
| FDA Guidance | Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005 |        |
| FDA Guidance | Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff Document issued on June 14, 2023.                                                       |        |
| FDA Guidance | Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff Document issued on September 27, 2023.            |        |

Summary:

Based on the performance as documented in the V&V Testing, the subject device was found to have a safe and effectiveness profile that is similar to the predicate device.

The following International Standards were used to develop and verify electrical safety, and EMC. GXR-Series Diagnostic X-Ray System has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports).

The subject device conform to all applicable aspects of 21CFR 1020.30.

**IX. CONCLUSIONS [21 CFR 807.92(b) (3)]**

The 510(k) Pre-Market Notification for GXR-series Diagnostic X-ray System, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs comparably to the predicate devices.