November 2, 2023

Gemss Healthcare Co., Ltd.
℅ Mr. Jiho Park
RA Manager
1F, 822, Bogwang-ro, Gwangtan-myeon
Paju-si, Gyeonggi-do 10952
SOUTH KOREA

Re: K230800
Trade/Device Name: Xvision-525, Horizon, Hi-300, Hi-500, Saturn-f Pf32, Saturn-f Pf40, Saturn-f Pf50
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: September 21, 2023
Received: September 21, 2023

Dear Mr. 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 (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 located 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230800

Device Name

XVISION-525, HORIZON, HI-300, HI-500, SATURN-F PF32, SATURN-F PF40, SATURN-F PF50

Indications for Use *(Describe)*

The XVISION-525 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.

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.

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510(k) Summary
K230800

510(k) Submission: K230800

This summary of 510(K) - safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 16, 2023

1. Applicant / Submitter

- GEMSS HEALTHCARE CO., LTD.
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2. Official Correspondent

- Dave Kim, MBA
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3. Device Information

- Trade/Device Name: XVISION-525, HORIZON, HI-300, HI-500, SATURN-F PF32, SATURN-F PF40, SATURN-F PF50
- Regulation Number: 21CFR 892.1680
- Regulation Name: Stationary x-ray system
- Device Class: Class II
- Product Code: KPR

4. Predicate Device

- K Number: K192364
- Manufacturer: DRGEM Corporation
- Trade Name: GXR-Series Diagnostic X-Ray System (Model: GXR-S)
- Regulation Number: 21CFR 892.1680
- Regulation Name: Stationary x-ray system
- Device Class: Class II
- Product Code: KPR

5. General Description

The XVISION-525 diagnostic X-Ray System (Models HORIZON, HI-300, HI-500, SATURN-F PF32, SATURN-F PF40, SATURN-F PF50) generates medical X-rays passing through the patient's body and a X-ray detector for producing radiographic images of the human anatomical structures.

The XVISION-525 diagnostic X-ray system consists of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, patient table, wall Bucky stand, and a x-ray tube, that operates on a high-frequency inverter method.

The user can select or change x-ray parameters easily using the operator control console. The AEC (Automatic Exposure Control) is an optional function to give the user control of exposure factors which can be optimized for different types of detectors selected, film or digital.

The XVISION-525 X-ray system does not include a detector.

6. Indication for use

The XVISION-525 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.

7. Comparison of the modified device to the cleared device

Descriptive Information	Subject Device	Predicate Device	Comparison
Manufacturer	GEMSS HEALTHCARE CO., LTD.	DRGEM Corporation	-
Device Name	• Category: X-ray equipment for diagnosis • Product: XVISION-525 • Model: XVISION-525, HORIZON, HI-300, HI-500, SATURN-F PF32, SATURN-F PF40, SATURN-F PF50	• Category: Diagnostic X-Ray System • Product: GXR-Series Diagnostic X-Ray System • Model: GXR-S	-
510(k) number	TBD	K192364	-
Regulatory Number	21CFR 892.1680	21 CFR 892.1680	Same
Product Code	KPR	KPR	Same
Regulatory Class	2	2	Same

Indications for Use		The XVISION-525 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.	The GXR-Series Diagnostic X-Ray System, (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S), 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.	Similar (Note 1)
Operation		For conventional radiography, an x-ray beam is generated and passed through a patient to a piece of film or a radiation detector, producing an image. Different soft tissues attenuate x-ray photons differently, depending on tissue density; the denser the tissue, the whiter (more radiopaque) the image. A single image is recorded for later evaluation.	For conventional radiography, an x-ray beam is generated and passed through a patient to a piece of film or a radiation detector, producing an image. Different soft tissues attenuate x-ray photons differently, depending on tissue density; the denser the tissue, the whiter (more radiopaque) the image. A single image is recorded for later evaluation.	Same
X-ray Generator	Models	PXR-401B, PXR-401BB, PXR-501B, PXR-501T, PXR-501TA	GXR-40, GXR-52, GXR-68, GXR-82 GXR-C32, GXR-C40, GXRC52	Similar (Note 2)
	Output Power	40kW, 50kW	32kW, 40kW, 52kW, 68kW, 82kW	
	kV Range	40~125kV, 40~150kV	40~125kV, 40~150kV	
	mA Range	10~500mA 10~630mA	GXR-32=10 to 400mA GXR-40=10 to 500mA GXR-52=10 to 640mA GXR-68=10 to 800mA GXR-82=10 to 1,000mA	
	Line voltage	220/230/240 VAC 100-120/220-240 VAC 380/400/440 VAC	220-230 VAC 380/400/480 VAC	
Tube Stand		Floor mount Type Floor Ceiling Type	Floor mount Type Floor Ceiling Type	Same (Note 3)

Bucky Table	4-way Tabletop Patient Table	4-way Tabletop Patient Table	
Wall Bucky Stand	Vertical Movement	Vertical Movement	
Image Acquisition	Detector not supplied with system	Detector not supplied with system (for GXR-S, SGXRS, FDR Smart FGXR-S)	

Note 1.

The Predicate device, GXR-Series Diagnostic X-Ray System has several models (GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S). GXR-SD, GXR-S, SGXR-S, FDR Smart ad FGXR-S do not have a detector. XVISION-525 diagnostic X-ray system, the subject device does not include a detector in its final product offering for the 510(k) clearance.

Example of digital X-ray detectors compatible with the XVISION-525 diagnostic X-ray system are provided below:

- Detector manufacture : Carestream Health, Inc
- Detector model : Focus 35C (FDA, K192512), Focus 43C (FDA, K200622)
- Image Processing Software: Image Suite (FDA, K100094)

Note 2.

The X-ray generator specifications are different from the predicate device.

1) Models: The predicate device has 7 different X-ray generator models depending on the output power, line voltage and kV range. We compare the subject device's X-ray generator models (PXR-401B, PXR-401BB, PXR-501B, PXR-501T, PXR-501TA) with GXR-40 and GXR-52 which has similar specifications.
2) Output:

- Model PXR-401B and PXR-401BB have the output power, 40kW. It is the same as the predicate device's X-ray generator, GXR-40 (40kW). Model PXR-501B, PXR-501T and PXR-501TA have the output power, 50kW. It is similar to the predicate device's X-ray generator, GXR-52 (52kW).
- Model PXR-401B and PXR-401BB has the kV rage, 40~125kV. It is the same as the predicate device's X-ray generator, GXR-40c (40~125kV). Model PXR-501B, PXR-501T and PXR-501TA has the kV rage, 40~150kV. It is the same as the predicate device's X-ray generator, GXR-52 (40~150kV).
- Model PXR-401B and PXR-401BB has the mA range, 10~500mA. It is the same as the predicate device's X-ray generator, GXR-40c (10~500mA). Model PXR-501B, PXR-501T and PXR-501TA has the kV range, 10~630mA. It is similar to the predicate device's X-ray generator, GXR-52 (10~640mA).

The subject device has been tested and verified about the safety and performance according to IEC 60601-1-3:2021, IEC 60601-2-28:2017 and IEC 60601-2-54: 2022.

3) Line voltage: Line voltage depends on the model.

- Model PXR-401B and PXR-501B have the input power (Single phase 220/230/240VAC).
- Model PXR-401BB has the input power (Single phase, 100-120/220-240VAC).
- Model PXR-501T has the input power (Three phase 380/400/440VAC).
- Model PXR-501TA has input power (Three phase 220/230/240VAC).

The predicate device's X-ray generator is connected to the line voltage 220-230VAC or 380/400/480VAC depends on the model

The subject device has been tested and verified about the electrical safety according to IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-3:2008+A1:2013, IEC 60601-2-28:2017 and IEC 60601-2-54:2018.

EMC test also has been conducted according to IEC 60601-1-2:2020

Note 3.

Tube Stand, Bucky Table and Wall Bucky Stand have the same purpose and movement as the predicate device.

The electrical and mechanical specification have been tested and verified according to IEC 60601-1:2005+A1:2012+A2:2020 and IEC 60601-2-54:2018.

EMC test also has been conducted according to IEC 60601-1-2:2020.

8. Software

The software is a firmware to control the X-ray Equipment for diagnosis (Models: XVISION-525). It is considered as Moderate Level of Concern. The primary function of the software is the operation of X-ray equipment for image acquisition. The user operates the X-ray Operation Unit to control the X-ray Control Unit. In X-ray Operation Unit, user can use Power On / Off, X-ray setting, irradiation, and options of X-ray Control Unit. The X-ray control unit carries out the X-ray setting and irradiation with the information transmitted from the X-ray operation.

The XVISION-525 diagnostic X-ray system does not include image processing software.

The software validation report was prepared in accordance with "FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

9. Electrical Safety and Electromagnetic Compatibility

Electrical Safety was verified according to the FDA recognized standards.

- IEC 60601-1:2005+A1:2012+A2:2020
- IEC 60601-1-3:2008+A1:2013,
- IEC 60601-2-28:2017
- IEC 60601-2-54:2018

EMC was verified according to the FDA recognized standard.

- IEC 60601-1-2:2014+A1:2020

10. Performance Testing – Bench

Essential performance for diagnostic X-ray system was verified according to the FDA recognized standard IEC 60601-2-54: 2018 Image Quality and Radiation Dose Test was also conducted with the predicate device.

11. Conclusion

The major consideration such as intended use and principle of operation, general function and application is the same as the predicate device. Although there are some differences, the safety and performance test reports are supported to the safety and effectiveness of the subject device. The test results show that the subject device does not raise any new potential safety and performance risks.

We conclude that the subject device is substantially equivalent to the predicate devices.