January 3, 2025

DK Medical System
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K242119
Trade/Device Name: Innovision-EXII
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: July 19, 2024
Received: July 19, 2024

Dear Dave Kim:

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) 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242119

Device Name

INNOVISION-EXII

Indications for Use *(Describe)*

INNOVISION-EXII is a stationery X-ray system intended for obtaining radiographic images of various anatomical parts of the human body, both pediatrics and adults, in a clinical environment. INNOVISION-EXII is not intended for mammography, angiography, interventional, or fluoroscopy use.

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

K242119

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared:

I. Submitter

Submitter's Information:	DK Medical Systems 52, Chupalsandan 1-Gil, Paengseong-Eup, Pyeongtaek-Si, Gyeonggi KR 17998 +82-2-535-7231 Sung-moon Hong (smhong@dk.co.kr)
Official Correspondent:	Dave Kim (davekim@mtechgroupllc.com) Mtech Group LLC 7505 Fannin St., Suite 610,Houston, TX 77054 +713-467-2607

II. Subject Device

Trade/proprietary Name	INNOVISION-EXII
Common or Usual Name	Digital Radiographic X-ray Systems
Regulation Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680
Product Code	KPR
Regulatory Class	Class II

III. Predicate Device

510K Number	K202572
Manufacturer	DR GEM
Device Name	GXR-Series Diagnostic X-Ray System
Regulation Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680
Product Code	KPR
Regulatory Class	Class II

IV. Compatibility:

INNOVISION-EXII

Detector	Clearance(s)
Vieworks VIVIX	FXRD-1717VA/VB (K181003), FXRD-2530VAW/VAW PLUS (K200418) FXRD-3643VAW/VAW PLUS (K200418), FXRD-4343VAW/VAW PLUS (K200418)

In the case of Innovation-EXII, it is compatible with the Detector listed in the table above.

V. Device Description

INNOVISION-EXII can receive X-ray signals from X-ray irradiation and digitize them into X-ray images by converting digital images to DICOM image format using Elui imaging software. INNOVISION-EXII is a general radiography X-ray system and not for mammography nor fluoroscopy. In addition, the system must be operated by a user who is trained and licensed to handle a general radiography X-ray system to meet the regulatory requirements of a Radiologic Technologist. Target areas for examinations include the head, spine, chest, and abdomen for diagnostic screening of orthopedic, respiratory, or vertebral discs. The system can capture a patient's postures, such as sitting, standing, or lying. This system can be used for patients of all ages, but it should be used with care for pregnant women and infants. The INNOVISION-EXII system has no part directly touching the patient's body.

VI. Indications for Use: 21 CFR 807 92 (a) (5)

INNOVISION-EXII is a stationery X-ray system intended for obtaining radiographic images of various anatomical parts of the human body, both pediatrics and adults, in a clinical environment.
INNOVISION-EXII is not intended for mammography, angiography, interventional, or fluoroscopy use.

VII. Technological characteristics: 21 CFR 807 92 (a) (6) Comparison Table

Item	Subject Device	Predicate Device	Impact of Differences
Device Name	INNOVISION-EXII Digital Radiography Systems	GXR-Series Diagnostic X-Ray System (K202572)	Not applicable
Manufacturer	DK Medical Systems	DRGEM Corporation	Not applicable
Model Number		GXR-S series	Not applicable
Indications for use	INNOVISION-EXII is a stationery X-ray system intended for obtaining radiographic images of various anatomical parts of the human body, both pediatrics and adults, in a clinical environment. INNOVISION-EXII is not intended for mammography, angiography, interventional, or fluoroscopy use.	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.	Equivalent
Conventional film/screen systems or CR cassettes	Comes with FDA cleared digital x- ray panels. Conventional film and CR cassettes can still be used.	Comes with FDA cleared digital x-ray panels. Conventional film and CR cassettes can still be used.	Equivalent Functionality
Operator console	GUI-based	Same	Similar Functionality
Power Source	AC LINE	AC LINE	Same

High Voltage generator			
Output Power	50kW, 80kW	32KW, 40KW, 52KW, 68KW, 82KW	The X-ray generator's output power is different.
Generator models	CPI CMP 200 (32kW to 100kW)	GXR-32, GXR- 40, GXR- 52, GXR-68, GXR- 82 (manufactured by DRGEM)	Yes, there is a difference. Models have been tested against International Safety and EMC Standards.
Line voltage	3 phase 400VAC ± 10%	220~230VAC, 380/400/480VA C,	Yes, there are differences in line voltage depending upon the system requirements.
Components / Parts			
Patient table			
Configuration model	TE-200	PBT-4, PBT-6, PDT-1	
Movement	*Up/down moving distance of table: 350mm ±10mm *Moving distance of left/right: 600mm ±10mm *Moving distance of forward/backward: 250mm±10mm	Longitudinal : 1000mm ± 500mm	The movement range is different.
Detector Stand			
Configuration model	DS-200	WBS, WBS-TM	
Dimension/weight	780(W) x 849(D) x 2224(H) mm / 125kg(256lbs)	659(W) x 445(D) x 1,599(H)mm / 110kg(242lbs) 659(W) x 445(D) x 1,749(H)mm / 113kg(249lbs) 659(W) x 445(D) x 1,919(H)mm / 116kg(255lbs) 659(W) x 445(D) x 2,169(H)mm / 120kg(264lbs)	The weight is different.

Ceiling suspended X-ray tube support			
Configuration model	Elin-T7	TS-FC6, TS-FC4, TS- FC2 TS-FM6, TS-CSA, TS- CSE	The tube stand model and rotation range are different.
Tube Rotation Angle	±180°	±135°	
X-ray tube			
Configuration model	canon E7869X Varex RAD-14 Diamond	E7239X, DXT-8M, E7242X, DXT-11M E7843X, DXT-10M E7876X, DXT-12M E7884X, E7252X DXT-14U, RAD-14U, DXT-15U, RAD-21 RAD-60, E7255FX, E4254FX	The X-ray tube configuration is different.
Max. kV	150kV	125kV, 150kV	
Collimator			
Configuration model	Ralco R225ACS	DXC-RML, DXC-RMH MCR, R108, R302A, R302MLP/A, R302MFMLP/A	The collimator model and configuration are different.
Detector			
Configuration model	FXRD-1717 VA/VB – K181003 FXRD-2530VAW/VAW PLUS – K200418 FXRD-3643VAW/VAW PLUS – K200418 FXRD-4343VAW/VAW PLUS – K200418 FXRD-2530FAW – K221512 FXRD-3643FAW - K221512 FXRD-4343FAW – K221512 FXRD-1717SA/SB – K122866 FXRD-1417SA/SB – K122866 FXRD-1417WA/WB – K122865 FXRD-1717NA/NB – K152894 FXRD-1417NAW/NBW – K163703 FXRD-1012NAW/NBW – K152885	VAREX, 4343R v3 - K172951 VAREX, 4336W v4- K161459 VAREX, XRpad2 3025 HWC-M- K161942 VAREX, XRpad2 4336 HWC-M- K161966 VAREX, XRpad2 4343 HWC-M- K181526 i-Ray, Mano4336WK201004 i-Ray, Mano4343WK201043 Vieworks, VIVIX-S1417N (NAW, NBW)-K163703 Vieworks, VIVIX-S1717N (NAW, NBW)- K152894 VAREX, 4343W- K161459	There are differences for detector. However, All the flat panel detectors have been previously cleared by 510(k). And the system has been tested and a risk analysis has been performed, and it has been concluded that there is no adverse effect on safety or effectiveness
Safety / Performance Test Standards	60601-1: 3.2 ed; 60601-1-2: 4.1 ed. 60601-4-2 (Essential performance), 60601-2-54 Edition 1.2, NEMA PS 3.1 - 3.20(2011) 21CFR 1020.30, 21CFR 1020.31	Same	Same

VIII. Non-clinical testing

Testing was performed successfully according to the following standards:

-Electrical safety and EMC
INNOVISION-EXII has been tested for electrical safety standard IEC 60601-1: 3.2 Ed and electromagnetic compatibility IEC 60601-1-2: 4.1 Ed.

The software validation and verification testing were also performed. The results of nonclinical testing indicate that the INNOVISION-EXII is as safe and effective as the predicate device.
Compliance evidences were submitted for the following standards:

Std #	Safety/EMC Standards Description	FDA Rec. Standard #
IEC 60601-1-3	Edition 2.2 2021-01, Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	12-269
IEC 60601-1-6	IEC 60601-1-6 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 60601-2-28	IEC 60601-2-28j Edition 3.0 2017-06 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, Edition 2.0 2022-09 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	12-317
IEC 60601-1-2 (EMC)	IEC 60601-1-2 Edition 4.1 2020-09. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances Requirements and tests.	19-8
IEC 62304:2006	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes	13-79
IEC 60601-1	Edition 3.2, 2020, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-4
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
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 PS3.1-3.20	DICOM Conformity	12-342
FDA 21CFR 1020	Electronic product: Performance Standard for Diagnostic X-ray System and Major Components	
FDA Guidance	Pediatric Information for X-ray Imaging Device Premarket Notifications dated November 28, 2017	
FDA Guidance	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: September 27, 2023	
FDA Guidance	Content of Premarket Submissions for Device Software Functions: JUNE 14, 2023	

Digital Imaging Software, Elui-W is a medical imaging software for acquiring patient's X-ray image, processing the readable images in working with diagnostic medical instrument, hospital information system and PACS. Elui program consists of Worklist mode that displays information of DICOM and of a patient whose images are to be acquired; Exam mode that displays images, irradiated body parts and filming conditions as well as conducts image processing; Database mode that stores and manages the acquired images and sends them to the server.

• Windows based graphic user interface

• X-ray generator control panel

• Unlimited procedure step

• Quick step-add feature and image maintenance feature by popup menu

• ROI changing and creation feature

• Marker feature (support the creation of unlimited number of markers by user)

• Multi-language support

• DAP meter (optional)

• Support DICOM and PACS

• High-performance post-processing feature

• Copy & Move Images

• Dose monitoring function

• Grid line suppression function

A detailed risk analysis was performed on the entire system, evaluating successful integration of the various components.

IX. Clinical testing

Clinical image evaluation of INNOVISION-EXII has been performed. The evaluation results demonstrated that INNOVISION-EXII generated images are adequate and suitable for expressing contour and outlines. The image quality including contrast and density are appropriate and acceptable for diagnostic exams.

Substantial Equivalence Discussion.

INNOVISION-EXII performs the same functions using the same technological methods to produce diagnostic x-ray images. In all material aspects, INNOVISION-EXII and the (GXR-Series Diagnostic X-Ray System) are substantially equivalent to each other.

X. Conclusion:

INNOVISION-EXII is substantially equivalent to the predicate device the (GXR-Series Diagnostic X-Ray System) Stationary Radiographic System. Both subject and predicate devices are same or very similar in the intended use, the design principle, the performance and the applicable standards. Therefore, DK Medical concludes INNOVISION-EXII is substantially equivalent with the (GXR-Series Diagnostic X-Ray System) Stationary Radiographic System .