



August 1, 2025

DK MEDICAL SYSTEMS Co., Ltd
% Dongha Lee
RA Consultant
KMC, Inc
#1709, G-Plus Tower, 123, Digital-ro 26-gil, Guro-gu
SEOUL, 08390
SOUTH KOREA

Re: K250790
Trade/Device Name: INNOVISION-DXII
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: March 14, 2025
Received: July 11, 2025

Dear Dongha Lee:

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,

A large, light blue watermark of the letters "FDA" is positioned behind the signature. The signature "Lu Jiang" is written in a black, cursive script over the watermark.

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

Indications for Use

510(k) Number (if known)

K250790

Device Name

INNOVISION-DXII

Indications for Use (Describe)

INNOVISION-DXII 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-DXII 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.

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510(k) #: K250790

510(k) Summary

Prepared on: 2025-07-24

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name

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Correspondent Contact

Mr. DongHa Lee

Correspondent Contact Email

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name

INNOVISION-DXII

Common Name

Stationary x-ray system

Classification Name

Stationary X-Ray System

Regulation Number

892.1680

Product Code(s)

KPR

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #

Predicate Trade Name (Primary Predicate is listed first)

Product Code

K242119

INNOVISION-EXII

KPR

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

INNOVISION-DXII is a stationary X-ray system using single and three phase power and consists of Tube, HVG(High voltage generator), Ceiling suspended X-ray tube support, Floor to Ceiling X-ray tube support, patient table, detector stand, and X-ray control console. The X-ray control console is a window-based software that can view X-ray images and a mobile console mounted on an Android-based board that only controls X-rays without viewer function.

After turning on the control unit, it irradiates the set X-ray on the exposure position properly generating X-ray in the inverter generator using IGBT. The compositions like supporters for X-ray tube and tables are used to supply power from the High Voltage generator.

When inverter type of Generator creates X-ray irradiation by certain exposure conditions, and X-ray penetrates the patient's body. X-ray information is transferred to a visible ray by a sensor's scintillator, and it turns to an electric signal through A-Si after transmitting photodiode to a TFT Array. This X-ray system is used with FDA cleared X-ray detectors. The electric signal is magnified and turned into a

digital signal to create image data. The image is transferred to the PC display by an Ethernet Interface, and it can be adjusted.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

INNOVISION-DXII is a stationary 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-DXII is not intended for mammography, angiography, interventional, or fluoroscopy use.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Indications for use is the same as the predicate device (K242119)

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device has the same operation principle to generate x-ray and clinical imaging.

The following technological characteristics differences exist between the subject device and the predicate device.

- 1) Operator console: X-ray control console that controls the subject device is operated by Android-based GUI software.
- 2) High Voltage Generator: The specifications (input line voltage and maximum output power) of the subject device is different from the predicate device. The line voltage is depending upon the system requirements.
- 3) X-ray tube: A used x-ray tube model (RAD-14) is the same as the predicate device. The other used x-ray tube models (E7239X, E7884X) of the subject device are different from the predicate device.
- 4) Collimator: The used collimator models of the subject device are different from the predicate device.
- 5) Detector: The subject device uses FDA cleared X-ray detectors. Some detector models were different from the predicate device. The detectors were verified about compatibility with the subject device.

The differences have been verified about the safety and performance by FDA recognized standards. The test results show that the differences did not raise new safety and effectiveness concerns.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Performance tests were performed with the follow consideration.

1. Bench testing (Functional test) according to IEC 60601-1-3, IEC 60601-2-28 and IEC 60601-2-54.

1) For X-ray Tube, Collimator and High Voltage Generator

- a) Tube Voltage accuracy
- b) Accuracy of X-RAY TUBE CURRENT
- c) Reproducibility of the RADIATION output in RADIOGRAPHY
- d) Linearity and constancy in RADIOGRAPHY
- e) Half Value Layer(HVL) / Total filtration
- f) Accuracy of Loading Time

2) For Detector

- a) System Instability
- b) Installation error
- c) System Error
- d) Image Loss, Deletion, and Restoration
- e) Image Save Error
- f) Image Information Error
- g) Image Transmission and Reception
- h) Header Verification
- i) Security
- j) Image Acquisition Test
- k) Search Function
- l) Application Function (ELUI S/W)
- m) Resolution

3) For Ceiling, Suspended, X-ray Tube Support, Detector Stand, Floating top table

- a) Moving distance

The bench test results show that the device is safe and essential performance effectiveness.

2. Clinical testing

: Clinical testing is not performed for the subject device as the detectors were already 510(k) cleared and the imaging software (Elui) is the same as the predicate device. There were no significant changes.