July 18, 2025

DK Medical Systems Co., Ltd
℅ Dongha Lee
RA Consultant
KMC, Inc
#1709, G-Plus Tower, 123, Digital-ro 26-gil, Curo-gu
SEOUL, 08390
SOUTH KOREA

Re: K250750
Trade/Device Name: Innovision-p5
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: March 11, 2025
Received: June 16, 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,

Lu Jiang

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

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.

510(k) Number *(if known)*
K250750

Device Name
INNOVISION-P5

Indications for Use *(Describe)*
The portable x-ray system may be used for diagnostic imaging of body extremities.
- Not for mammography use
- This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

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 (K250750)

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

July 16, 2025

I. Submitter

Submitter's Information:	DK Medical Systems Co., Ltd 52, Chupalsandan 1-Gil, Paengseong-Eup, Pyeongtaek-Si, Gyeonggi KR 17998 +82-2-535-7231 Sung-moon Hong (smhong@dk.co.kr)
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II. Subject Device

Trade/proprietary Name	INNOVISION-P5
Common or Usual Name	Portable X-ray System
Regulation Name	Mobile X-ray System
Regulation Number	21 CFR 892.1720
Product Code	IZL
Regulatory Class	Class II

III. Predicate Device

510K Number	K210479
Manufacturer	MinXray Inc.
Device Name	IMPACT and X-Ranger
Regulation Name	Mobile X-ray System
Regulation Number	21 CFR 892.1720
Product Code	IZL, MQB
Regulatory Class	Class II

IV. Device Description

This portable X-ray system (Model: INNOVISION-P5) consists of an LCD display with up and down soft keys for controlling the kV settings. It includes a line-powered X-ray generator (transformer), an X-ray tube assembly, a collimator, a support stand, imaging processing software, and a digital flat-panel detector. The INNOVISION-P5 is a battery-operated, portable X-ray system designed for use with a flat-panel detector

The major components of the X-ray main unit include handle, enclosure, main control panel, system control board, high-voltage tank, inverter, collimator (beam limiter), system control software running on the system control board, imaging processing software, and detector. The system control software is for real-time interaction and control with various circuit modules inside the X-ray generator. The software responds to user operations on the control panel. The user can adjust and control the kV and mAs parameters, and the software displays the parameters or directly load the APR parameters. The software loads the control data from X-ray output into the high-voltage generation control circuit of the system control board, and control the high-voltage tank to generate high-voltage to excite the X-ray tube inside to emit X-rays, control the switch of the collimator, and monitor the working status of the device, and control the display of the status indicators.

The system is for X-ray imaging and diagnosis in facilities with portable or fixing sites.

This INNOVISION-P5 is not intended for mammography.

The device can be used with an X-ray flat panel detector, a computer for receiving and detecting signal results and an image processing software. Under certain exposure conditions, the inverter generator irradiates X-rays and the X-rays penetrate the patient's body. The Software (Elui-P) and portable x-ray unit communicate via Bluetooth to send/receive data to operate the product. The X-ray information is turned into electrical signals by a detector. The electrical signals are magnified and converted into digital signals to create image data. The image is sent to the image processing software (Elui-P) via Wifi. This portable X-ray System is designed for handheld or stand-mounted imaging. Model INNOVISION-P5 can be configured to an optional portable stand that complies with IEC 60601- 1 safety standard. The recommended maximum load that the stand can safely carry is 6kgs to ensure the mechanical stability and effectiveness of the device.

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

.	Subject Device	Predicate Device	Comparison
Manufacturer	DK Medical Systems Co., Ltd	MinXray, Inc.	-
Device Name	INNOVISION-P5	IMPACT and X-Ranger	-
K number	K250750	K210479	-
Indications for use	The portable x-ray system may be used for diagnostic imaging of body	This is a portable X-ray system with following limitations of use: The	Same

	extremities. - Not for mammography use - This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	device may be used for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients, unless imaging body extremities - Not for mammography use - This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	
Size : Body	293.4 X 151.8 X 256.5mm	219 X 350 X 190 mm	Different 1
Weight	3.5kg	7.5kg	
User interface	Soft touch push buttons	Soft touch push buttons	Same
Energy source	Li-Polymer Rechargeable Battery 29.6V, 1470mAh	Lithium-ion Rechargeable Battery 57.6DC, 1450mAh	Different 2
Exposure times	0.04 ~ 2.00 sec (20 Steps)	0.01 ~ 1.0 sec (0.01 sec step) (High Power Mode) 0.01 ~ 0.3 sec (0.01 sec step)	Similar
Memory settings	10 APR Memories	5 memories via pushbutton	Similar
High Voltage Generator			
Maximum Output Power	720W	1.35kW	Different 3
kV Range	50-90kVp	40-90kVp	Similar
mA Range	10mA @ 50-70kV / 0.4~20 mAs 8mA @ 71-90kV / 0.4~16 mAs	20mA @ 40-60 kV 15mA @ 62-80 kV 10mA @ 82-90 kV (High Power Mode) 15mA @ 82-90 kV	Different 3
X-ray Tube			
Model	OX/90	D-0814	Different 4
Focal spot	0.5mm	0.8mm	

Target material	Tungsten	Tungsten	
Target degree	19 degree	16 degree	
Inherent filtration	0.5mmAl	0.8mmAl	
Anode heat storage	10kJ	7kJ	
Collimator			
X-ray Field	Min. ≤ 5x5cm@100cm SID Max. ≤ 47x47cm@100cm SID	Max. X-ray Field: 35x35cm@100cm SID	Different 5
Inherent filtration	0.5mmAl	0.5mmAl	Same
Adjustment Method	Manual	Manual	Same
Flat Panel Detector			
FDA cleared device	K223930	K191451	Different 6
Manufacturer	H&abyz Co., Ltd.	CareRay	
Models	A1717MCW, A1417MCW, F1417MCW	CareView 1500Cw	
Software			
Model	Elui-P	Q&R Imaging Software	Different 7
Main Function	Image processing Image acquisition Image transmission Image displaying Parameter control	Image processing Image acquisition Image transmission Image displaying Parameter control	

1) Difference

No	Differences	Explanation
1	Size, Weight	The size and weight of the subject device is different from the predicate device. The differences have been tested and verified about the safety accordance with FDA recognized standard. The results show that it did not raise new safety concerns.
2	Energy source	Both devices are DC-powered by battery while charged with AC-power. Although there are differences in battery specifications, the differences have been tested and verified about the safety and performance accordance with FDA recognized standards. The results show that it did not raise new safety and effectiveness concerns.
3	High Voltage Generator	The specifications (maximum output power, kv and mA range) of the subject device is different from the predicate device.

		The differences have been tested and verified about the safety and performance accordance with FDA recognized standards. The results show that it did not raise new safety and effectiveness concerns.
4	X-ray tube	The specifications (Focal spot, Target degree, Inherent filtration and Anode heat storage) of the subject device is different from the predicate device. The differences have been tested and verified about the safety and performance accordance with FDA recognized standards. The results show that it did not raise new safety and effectiveness concerns.
5	Collimator	The specification (X-ray Field) of the subject device is different from the predicate device. The difference has been tested and verified about the safety and performance accordance with FDA recognized standards. The results show that it did not raise new safety and effectiveness concerns.
6	Flat Panel Detector	The used detector is different from the predicated device. The detector for the subject has been cleared, K223930. The safety and performance has been reviewed by FDA according to the FDA 510(K). Testing with the system about the safety and performance has been conducted accordance with FDA recognized standards. The results show that it did not raise new safety and effectiveness concerns.
7	software	Digital Imaging Software, Elui is a medical imaging software. The main functions are the same as the predicate device but the software unit specifications and architecture are different. The software has been verified and validated according to the FDA recognized standard and FDA guidance. The results show that it did not raise new safety and effectiveness concerns.

VI. Safety and Performance Data

The following safety and performance data were provided in support of the substantial equivalence determination.

1) Safety and Non-clinical testing

: Safety and Non-clinical tests were conducted to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device. We claim conformance to the following standards and guidance:

Stadand #	Title	FDA Recognition #
IEC 60601-1	Edition 3.2, 2020-08, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-49
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.	19-36
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	12-336

IEC 60601-2-28	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	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	12-348
IEC 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
IEC 62304:2006	Edition 1.1, 2015-06, Medical device software - Software life cycle processes	13-79
IEC 62133-2	Edition1.0, 2017-02, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	19-33
IEC 81001-5-1	Edition 1.0 2021-12, Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle.	13-122
AAMI TIR57:2016	2016, Principles for medical device security – Risk management	13-83
NEMA PS 3.1-3.20	2023e, Digital Imaging and Communications in Medicine (DICOM) Set	12-352
FDA Guidance	2023.09, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.	
FDA Guidance	2023. 06, Content of Premarket Submissions for Device Software Functions.	

2) Clinical Image Evaluation

X-ray images acquired using the subject device were evaluated for image quality by a clinical expert. This device meets the diagnostic radiography standards by producing high-resolution and detailed images. Furthermore, it has been evaluated that this device effectively supports diagnostic purposes and delivers reliable performance in clinical applications.

VII. Conclusion:

Based on the comparison and analysis above, the proposed device has same indications for use, similar performance, equivalence safety and effectiveness as the predicate device.

The differences above between the proposed device and predicate device do not affect the indications for use, technology characteristics, safety and effectiveness.

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

The Image quality was analyzed and evaluated by non-clinical evaluation and by a qualified expert. The results show that the image meets the quality and clinical adequacy as well as the legally marketed device.

No issues are raised regarding to safety and effectiveness.

The subject device is determined to be Substantially Equivalent (SE) to the predicate device.