April 10, 2026

Dk Medical Systems Co., Ltd.
% Dong Ha Lee
RA Consultant
KMC, Inc.
#509, Daerung Post Tower, 43,
Digital-Ro 26-Gil, Guro-Gu,
SEOUL, 08389 SOUTH KOREA

Re: K253446
Trade/Device Name: AeroDR TX c02
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: March 13, 2026
Received: March 13, 2026

Dear Dong Ha 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

FDA Digitally signed by GABRIELA M. RODAL -S for

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)*
K253446

Device Name
AeroDR TX c02

Indications for Use *(Describe)*

AeroDR TX c02 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. AeroDR TX c02 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) #: K253446

510(k) Summary

Prepared on: 2026-03-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DK MEDICAL SYSTEMS Co., Ltd
Applicant Address	52, Chupalsandan 1-Gil, Paengseong-Eup Pyeongtaek-Si Gyeonggi-do 17998 Korea, South
Applicant Contact Telephone	82-2-535-7231
Applicant Contact	Mr. YoungWoo Kang
Applicant Contact Email	ywkang@dk.co.kr
Correspondent Name	KMC, Inc
Correspondent Address	#509, Daerung Post tower, 43, Digital-ro 26-gil, Guro-gu Seoul 08389 Korea, South
Correspondent Contact Telephone	82-70-8965-5554
Correspondent Contact	Mr. DongHa Lee
Correspondent Contact Email	dhlee@kmcerti.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AeroDR TX c02
Common Name	System, X-Ray, Stationary
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)

AeroDR TX c02 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. AeroDR TX c02 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.
The x-ray detectors used with the system are unchanged from the predicate (K242119).
The device software is unchanged from the predicate and it has been cleared as cybersecure under K242119.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

AeroDR TX c02 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.
AeroDR TX c02 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 (existing device) (K242119).

Technological Comparison 21 CFR 807.92(a)(6)

The predicate device (existing device) is an own manufactured device cleared by FDA (K242119).
The subject device (Modified device) is the same as the predicate device (existing device) except for the below.
1. Trade Name
   1) Trade name is changed. (AeroDR TX c02)
2. X-ray System Components (Configuration)
   1) Alternate X-ray tube is changed. (E7884X)
   2) Alternate Collimator is added. (BL-80)
   3) Patient table is changed. (PT5-G1 K)
   4) X-ray detector stand is changed. (WS5-G1 K)
   5) Ceiling suspended x-ray tube support is changed. (CS5-G1 K)

The differences (changes) do not affect to the x-ray image generated from the x-ray system.
The differences (changes) between the subject device and predicate device were tested and verified about the safety and effectiveness accordance with FDA recognized standards. The test results show that it did not raise new safety and effectiveness concerns.
The subject device is determined to be Substantially Equivalent (SE) to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Tests
1. EMC and Safety test
: EMC and Safety tests were conducted to verify that the subject device (modified device) met all design changes as it is Substantially Equivalent (SE) to the predicate device (existing device). We claim conformance to the following standards.
1) IEC 60601-1 (Edition 3.2, 2020-08)
2) IEC 60601-1-2 (Edition 4.1, 2020-09)
3) IEC 60601-1-3 (Edition 2.2, 2021-01)
4) IEC 60601-2-28 (Edition 3.0, 2017-06)
5) IEC 60601-2-54 (Edition 2.0, 2022-09)

2. Software and Cybersecurity test
: The device software and cybersecurity characteristics are unchanged from the predicate and the test results have been reviewed under K242119.

3. Performance test
: X-ray image quality are unchanged form the predicate and the clinical image evaluation results have been reviewed under K242119.

Conclusion
: The differences (changes) do not affect to the x-ray image generated from the x-ray system.
The differences (changes) between the subject device and predicate device were tested and verified about the safety and effectiveness accordance with FDA recognized standards. The test results show that it did not raise new safety and effectiveness concerns.
The subject device is determined to be Substantially Equivalent (SE) to the predicate device.