April 30, 2026

Canon Inc.
% Saori Sawaki
Business Manager, Regulatory Consultant
Ken Block Consulting LLC
3400 N Central Expy Ste 100-265
RICHARDSON, TX 75080

Re: K252503
Trade/Device Name: Intelligent NR
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, MQB
Dated: March 30, 2026
Received: March 31, 2026

Dear Saori Sawaki:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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)*
K252503

Device Name
Intelligent NR

Indications for Use *(Describe)*
As a part of the Canon radiography system, the CXDI Control Software when used with a compatible Canon detector is intended to provide digital image capture, processing, and display for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures including specialist areas like intensive care, trauma, and pediatric work.
It is also used for generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers.
As part of the CXDI Control Software, the Intelligent NR utilizes artificial intelligence based algorithms to reduce noise in fluoroscopic images.
Not intended for mammography 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K252503

Applicant/ Sponsor: Canon Inc.
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Contact Person:

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Subject Device	Manufacturer:	Canon Inc.
	Trade Name:	Intelligent NR
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Product Code:	OWB
	Subsequent Product Codes:	MQB
	Regulation Number:	21 CFR 892.1650
	Regulation Name:	Image-intensified fluoroscopic x-ray system
	Class:	II
Predicate Device:	Clearance:	K232298
	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Product Code:	OWB
	Subsequent Product Codes:	MQB
	Regulation Number:	21 CFR 892.1650
	Regulation Name:	Image-intensified fluoroscopic x-ray system
	Class:	II
Reference Device:	Clearance:	K212269
	Manufacturer:	Canon Inc.
	Trade Name:	Intelligent NR
	Classification Name:	Solid state x-ray imager (flat panel/digital imager)
	Classification Product Code:	MQB
	Regulation:	21 CFR 892.1680, Stationary x-ray system
	Class:	II

Device Description:

The Intelligent NR (Intelligent Noise Reduction) function is a part of the CXDI Control Software for the Canon detectors (with version 3.13 of the CXDI Control Software) that makes use of the Intelligent NR function to reduce noise for X-ray images taken using the Canon detectors. The Intelligent NR function was developed using machine-learning and trained by using an existing clinical image database to learn the characteristics of noises and display/create noise reduced images and videos. The Intelligent NR function does not perform machine learning after release to users. The CXDI control software, which Intelligent NR is a part

of, provides system control, controls GUI on the monitor, and processes images. The Intelligent NR function works on a PC and displays to a monitor. The Intelligent NR function is used in conjunction with the cleared Canon detectors compatible with CXDI Control Software V3.13. The firmware within compatible Canon detectors to be used with this device is unchanged, and no firmware update is necessary for compatibility with Intelligent NR.

Indications for Use:

As a part of the Canon radiography system, the CXDI Control Software when used with a compatible Canon detector is intended to provide digital image capture, processing, and display for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures including specialist areas like intensive care, trauma, and pediatric work.
It is also used for generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers.
As part of the CXDI Control Software, the Intelligent NR utilizes artificial intelligence based algorithms to reduce noise in fluoroscopic images.
Not intended for mammography applications.

Summary of Technological Characteristics:

The Indications for Use statement for the proposed device differs slightly from that of the predicate device. This distinction is due to the predicate device being a sensor detector unit, whereas the proposed device is software designed to operate with a compatible Canon sensor detector, such as the predicate device. Additionally, the intended use of the subject software function has been added to the Indications for Use Statement to reflect the core purpose of this submission, which is supported by the performance testing conducted. Despite these differences, the intended use and clinical application of both devices are the same.

The Intelligent NR for dynamic imaging is a newly implemented optional fluoroscopy imaging function in the proposed device. This function utilizes a machine learning algorithm to automatically reduce image noise in fluoroscopy data. The same algorithm was previously used in the reference device to reduce noise in radiology images.

The addition of the Intelligent NR function has been thoroughly evaluated and verified through validation activities. These assessments support the conclusion of substantial equivalence and demonstrate that the differences between the proposed and predicate devices do not introduce new questions regarding safety or effectiveness.

	Proposed Device	Predicate Device	Reference Device
Trade Name	Intelligent NR	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1	Intelligent NR
510(k) Submitter [Number]	Canon Inc.	Canon, Inc. [K232298]	Canon Inc. [K212269]
Indication for Use	As a part of the Canon radiography system, the CXDI Control Software when used with a compatible Canon detector is intended to provide digital image capture, processing, and display for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures including specialist areas like intensive care, trauma, and pediatric work. It is also used for generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers. As part of the CXDI Control Software, the Intelligent NR utilizes artificial intelligence based algorithms to reduce noise in fluoroscopic images. Not intended for mammography applications.	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1 is indicated for use in generating radiographic images of human anatomy to replace the radiographic film/screen systems in all general purpose diagnostic procedures. It is also used for generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers. Not intended for mammography applications.	As a part of the Canon radiography system, the CXDI Control Software when used with a compatible Canon detector is intended to provide digital image capture, processing, and display for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures including specialist areas like intensive care, trauma, and pediatric work. This device is not intended for fluoroscopic, angiographic, or mammography applications.
Application / Intended Use	Fluoroscopy and General Radiology	Fluoroscopy and General Radiology	General Radiology
Software / Version	CXDI Control Software V3.13	CXDI Control Software V3.11	CXDI Control Software V3.10
Optional Radiology Image Processing Functions	Free Rotating, Scatter Correction, Enhancement Control, Intelligent NR function, One Shot Long Length Imaging, Multiple Shot One exposure per image	Free Rotating, Scatter Correction, Enhancement Control	Free Rotating, Scatter Correction, Enhancement Control, Intelligent NR function, One Shot Long Length Imaging, Multiple Shot One exposure per image
Optional Fluoroscopy Imaging Function	Scatter Correction Intelligent NR for Dynamic Imaging	Scatter Correction	N/A

Summary of Non-Clinical/ Clinical Test Data:

Tests were performed on the CXDI Control Software, including the Intelligent NR function, and demonstrated that the device is safe and effective, performs comparably to the predicate device, and is substantially equivalent to the predicate and reference devices. Tests included verification/validation testing to internal software specifications and image comparisons involving flat panel display images with noises reduced by the Intelligent NR, comprising qualitative assessments of spatial resolution, contrast-to-noise ratio (CNR), and a reader imaging performance evaluation. The contrast transfer function (CTF) with Intelligent NR showed no change. Contrast was maintained, and no degradation in spatial resolution was observed. The CNR with Intelligent NR was improved, measuring approximately 1.1 to 1.5 times higher than that of the conventional NR. The reader evaluation was performed by two independent physicians, each of whom assessed archived clinical cases processed with both the conventional noise-reduction function and

Intelligent NR. The readers confirmed that image quality improved in descending order of processing intensity, and in all cases, images processed with Intelligent NR were judged superior to those processed with conventional NR. The risks and hazardous impacts of the device modification were analyzed by FMEA methodology. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented as part of product design. The overall assessment concluded that all identified risks and hazardous conditions were successfully mitigated and accepted. The proposed Intelligent NR demonstrated compliance with IEC 62304:2015 and has cybersecurity controls in place. Together, these verification/validation activities successfully demonstrated that the Intelligent NR correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the Intelligent NR.

As reported in prior submissions to FDA, the compatible detectors comply with the U.S. Performance Standard for radiographic equipment and with relevant voluntary safety standards for Electrical Safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1, 60601-1-2, 60601-1-3, and 60601-2-32.

Conclusion:

Canon Inc. considers the Intelligent NR to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in application/intended use, principles of operation, functional design, and established medical use.