September 17, 2021

Canon Inc.
% Mr. Gregory Woodard
Biomedical Engineer
Ken Block Consulting
800 East Campbell Road, Suite 202
RICHARDSON TX 75081

Re: K212269
Trade/Device Name: Intelligent NR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: July 19, 2021
Received: July 20, 2021

Dear Mr. Woodard:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212269

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. This device is not intended for fluoroscopic, angiographic, or 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.

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510(k) SUMMARY

Submitter: Canon Inc.
30-2 Shimomaruko, 3-chrome
Ohta-ku, Tokyo 146-8501 Japan

Contact Person: Mr. Akira Hirai
General Manager
TEL: 81-3-3758-2111;
FAX: 044-739-6695
hirai.akira@mail.canon

Date Prepared: July 19, 2021

Submission Type: Traditional 510(k) Submission

Proposed Device:

Manufacturer:	Canon Inc.
Trade Name:	Intelligent NR
Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name:	Stationary X-ray System
Classification:	892.1680, Stationary X-ray System
Product Code:	MQB

Predicate Device:

510k Number:	K190368
Manufacturer:	Canon Inc.
Trade Name:	Enhanced Feature Software Pack for CXDI Series
Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name:	Stationary X-ray System
Classification:	892.1680, Stationary X-ray System
Product Code:	MQB

Device Description: The Intelligent NR (Intelligent Noise Reduction) function is a part of the CXDI Control software for the Canon detectors (with version 3.10 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 create noise reduced images. 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 V3.10. The firmware within compatible Canon detectors to be used with this device is unchanged, and no firmware update is necessary for compatibility with the Intelligent NR.

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. This device is not intended for fluoroscopic, angiographic, or mammography applications.

Summary of Technological Characteristics:

Comparison with the predicate devices shows the characteristics of the proposed device to be substantially equivalent to the predicate device.

	Proposed Device	Predicate Device
Trade Name	Intelligent NR	Enhanced Feature Software Pack for CXDI Series
510(k) Submitter [Number]	Canon Inc. [TBD]	Canon Inc. [K190368]
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. This device is not intended for fluoroscopic, angiographic, or mammography applications.	As a part of the CXDI series radiography system, the CXDI Control Software when used with a compatible CXDI 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.
Software / Version	CXDI Control Software V3.10	CXDI Control Software V2.17
Scatter Correction	An image can be created (with high contrasts) by using software algorithm, in clinical field, without a grid	An image can be created (with high contrasts) by using software algorithm, in clinical field, without a grid
One Shot Long Length Imaging	One exposure to obtain images across multiple detectors, automatically stitched together with ability to make manual adjustments after the automatic stitching.	One exposure to obtain images across multiple detectors, automatically stitched together with ability to make manual adjustments after the automatic stitching.
Intelligent NR Function	Process to reduce noise from the taken images by using function machine trained on characteristics of noises included in X-ray image signals using an existing clinical image database	N/A

The Operation Manual provides detailed instructions and information for safe and effective use of the device, and users are expected to adhere to the instructions and other information. The Operation Manual explains how to use the software and other equipment.

Performance:

The hardware within the Canon Digital Radiography Canon Detectors used with the Intelligent NR has not been modified, the detectors have the same performance, biocompatibility, effectiveness, and safety and is substantially equivalent to the predicate device. 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.

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. The wireless detectors also comply with the FCC test standard for SAR, specifically 47CFR 2.1093 and for EMI test regulations FCC Part 15 Subpart B:2012 Class A and ICES-003 Issue 5:2012 Class A.
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 primary intended use, principles of operation, functional design, and established medical use.