February 4, 2022

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

Re: K220098
Trade/Device Name: Digital Radiography CXDI-Pro, Digital Radiography D1
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: January 11, 2022
Received: January 12, 2022

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,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
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)*
K220098

Device Name
DIGITAL RADIOGRAPHY CXDI-Pro
DIGITAL RADIOGRAPHY D1

Indications for Use *(Describe)*
The DIGITAL RADIOGRAPHY CXDI-Pro / D1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is 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.

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510(k) SUMMARY **K220098**

Applicant/Sponsor:	Canon Inc. 9-1 Imaikami-cho Nakahara-ku, Kanagawa 211-8501 Japan	
Contact Person:	Mr. Akira Hirai General Manager TEL: 81-3-3758-2111; FAX: 044-739-6695 hirai.akira@mail.canon	
Date Prepared:	January 28, 2022	
Submission Type:	Special 510(k) Submission	
Proposed Device:	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-Pro DIGITAL RADIOGRAPHY D1
	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:	K212553
	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-Pro DIGITAL RADIOGRAPHY D1
	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 DIGITAL RADIOGRAPHY CXDI-Pro, also called the DIGITAL RADIOGRAPHY D1, (hereinafter referred to as CXDI-Pro) is a solid-state x-ray imager. The CXDI-Pro is a series of detectors, and in the predicate device consists of the CXDI-703C Wireless detector unit, also called the AR-D3543W detector. The detector intercepts x-ray photons, and the scintillator emits visible spectrum photons that illuminate an array of photodetectors that create electrical signals. After the electrical signals are generated, the signals are converted to digital values, and the images will be displayed on monitors. The digital image can be communicated to the operator console via a wired or wireless connection.

The subject of this Special 510(k) submission is a change to the CXDI-Pro add a detector, the CXDI-403C Wireless (also called AR-D4343W) to the CXDI-Pro series of detectors. In addition, a Detector Stand (DS-01) and a new Battery Charger (BC-01) have been added as optional components to be used with the proposed CXDI-Pro detectors (CXDI-703C Wireless and CXDI-403C Wireless), the sleep to ready cycle time for the proposed CXDI-Pro detectors has been decreased, and the CXDI Control Software has been updated from V3.10.0.3 to V3.10.0.8 to add the Intelligent NR function (cleared under K212269) and apply some bug fixes. Together, these changes make up the CXDI-Pro.

Indication for Use: The Indication for Use statement is identical to the predicate device. The intended use of the proposed device, as described in the labeling, has not changed as a result of the modification(s).

The DIGITAL RADIOGRAPHY CXDI-Pro / DIGITAL RADIOGRAPHY D1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

Summary of Technological Characteristics: Comparison with the predicate device shows the characteristics of the proposed modifications (addition of a new detector and additional optional accessories) to the CXDI-Pro to be substantially equivalent to the predicate device.

	Proposed Device	Predicate Device	
Trade Name	DIGITAL RADIOGRAPHY CXDI-Pro / DIGITAL RADIOGRAPHY D1	DIGITAL RADIOGRAPHY CXDI-Pro / DIGITAL RADIOGRAPHY D1	
510(k) Submitter [Number]	Canon Inc. [K220098]	Canon Inc. [K212553]	IDENTICAL
Indication for Use	The DIGITAL RADIOGRAPHY CXDI-Pro / DIGITAL RADIOGRAPHY D1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	The DIGITAL RADIOGRAPHY CXDI-Pro / DIGITAL RADIOGRAPHY D1 provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	IDENTICAL
Application	General Radiography	General Radiography	IDENTICAL
Case Material	Magnesium alloy	Magnesium alloy	IDENTICAL
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]	IDENTICAL
Pixel Pitch	140µm	140µm	IDENTICAL
Spatial Resolution	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]	IDENTICAL
IP Level	IP55	IP55	IDENTICAL
Detector(s)	CXDI-703C Wireless (AR-D3543W) CXDI-403C Wireless (AR-D4343W)	CXDI-703C Wireless (AR-D3543W)	MODIFIED
Components	Detector (Sensor) Battery Charger (BC-1A) Battery Pack (LB-4A) X-ray Interface Box (XB-1A) Power Box (PB-01) Wiring Cable (WC-01) PC Connection Cable (CP-01) Ready Indicator (RI-3A) Detector Stand (DS-01) Battery Charger (BC-01)	Detector (Sensor) Battery Charger (BC-1A) Battery Pack (LB-4A) X-ray Interface Box (XB-1A) Power Box (PB-01) Wiring Cable (WC-01) PC Connection Cable (CP-01) Ready Indicator (RI-3A)	MODIFIED
Software	CXDI Control Software V3.10.0.8	CXDI Control Software V3.10.0.3	MODIFIED
Photographing Mode	Standard Synchronization Mode, Non Generator Connection Mode	Standard Synchronization Mode, Non Generator Connection Mode	IDENTICAL
Wireless Communication	IEEE 802.11n/ac/a/g/b 2.4GHz/5GHz Bluetooth Low Energy	IEEE 802.11n/ac/a/g/b 2.4GHz/5GHz Bluetooth Low Energy	IDENTICAL
Cycle Time: Sleep to Ready Time	Cycle Time is less than 5 sec when the storage time is set to 100ms	Cycle Time is 7 sec when the storage time is set to 100ms	MODIFIED

The User's and Installation Manuals provide 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 User's Manual explains how to use the detector and other equipment. Connected medical equipment, such as x-ray generators, must comply with IEC 60601-1.

Performance: The fundamental scientific technology of the CXDI-Pro has not been modified. The changes are the addition of a new detector, CXDI-403C Wireless (AR-D4343W); the addition of optional accessories, a Detector Stand (DS-01) and a different Battery Charger (BC-01); a decrease in the sleep to ready cycle time; the update to the CXDI Control Software from 3.10.0.3 to 3.10.0.8; and the update to the detector firmware from 01.00.00.03 to 01.00.02.00.

Evaluation of the addition of the new detector and optional accessories confirmed that the changes did not impact CXDI-Pro conformance 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, 60601-2-54, 60601-1-6, and IEC 60529.

These verification/validation activities successfully demonstrated that the device continues to meet the standards for the areas impacted by the modifications to the predicate device and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation activities conducted support a determination of substantial equivalence for the CXDI-Pro.

Conclusion: Canon Inc. considers the CXDI-Pro 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.