September 30, 2021

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

Re: K212553
Trade/Device Name: DIGITAL RADIOGRAPHY CXDI-Pro D1
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB

Dear Gregory Woodard:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 9, 2021. Specifically, FDA is updating this SE Letter (Typo in the Trade Name) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Laurel Burk, OHT7: Office of In Vitro Diagnostics and Radiological Health, 301-796-5933, laurel.burk@fda.hhs.gov.

Sincerely,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.09.30 14:31:00 -04'00'

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

September 9, 2021

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

Re: K212553
Trade/Device Name: DIGITAL RADIOGRAPHY CXDI-Pro, D1
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: August 12, 2021
Received: August 13, 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,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.09.09 10:30:16 -04'00'

, 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)*
K212553

Device Name
DIGITAL RADIOGRAPHY CXDI-Pro
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) SUMMARY

K212553

Applicant/Sponsor:	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:	August 12, 2021	
Submission Type:	Special 510(k) Submission	
Proposed Device:	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-Pro 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:	K170332
	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-710C
	Common Name:	Solid State X-ray Imager
	Classification Name:	Stationary X-ray System
	Classification:	892.1680, Stationary X-ray System
	Product Code:	MQB
Reference Devices:	510k Number:	K192632
	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-702C
	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 D1, (hereinafter referred to as CXDI-Pro) is a solid-state x-ray imager. The CXDI-Pro is a series of detectors, currently consisting 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 value 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 DIGITAL RADIOGRAPHY CXDI-710C Wireless (hereinafter referred to as CXDI-710C) to make the CXDI-Pro. This change will remove the Docking Station, Multi Box, and Status Indicator as optional components and add the X-ray Interface Box and Power Box as optional components. The software has been updated from CXDI Control Software V2.16 to CXDI Control Software V3.10. The case material has been changed from fiberglass to magnesium alloy. Bluetooth function has been added, and Standalone mode has been removed as a photographing mode. 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 modified device, as described in the labeling, has not changed as a result of the modification(s).

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.

Summary of Technological Characteristics: Comparison with the predicate devices shows the characteristics of the proposed modifications (changes to the optional accessories, software change from V2.16 to V3.10, change in case material from fiberglass to magnesium alloy, addition of Bluetooth, and removal of Standalone mode) to the CXDI-Pro to be substantially equivalent to the predicate device.

	Proposed Device	Predicate Device	Reference Devices	
Trade Name	DIGITAL RADIOGRAPHY CXDI-Pro / D1	DIGITAL RADIOGRAPHY CXDI-710C	DIGITAL RADIOGRAPHY CXDI-702C	
510(k) Submitter [Number]	Canon Inc. [TBD]	Canon Inc. [K170332]	Canon, Inc. [K192632]	IDENTICAL
Indication for Use	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.	The DIGITAL RADIOGRAPHY CXDI-710C Wireless 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-702C Wireless 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	General Radiography	IDENTICAL
Case Material	Magnesium alloy	Fiberglass	Magnesium Alloy	MODIFIED
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]	IDENTICAL
Pixel Pitch	140µm	125µm	125µm	MODIFIED
Spatial Resolution	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]	IDENTICAL
IP Level	IP55	IPX7	IP54	MODIFIED

Standard Components	Detector (Sensor), Battery Pack (LB-4A), Documentation (Manuals)	Detector (Sensor), Battery Pack (LB-4A), Documentation (Manuals)	Detector (Sensor), Battery Pack (LB-4A), Documentation (Manuals)	IDENTICAL
Optional Components	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)	Docking Station (DS-4A), Battery Charger (BC-1A), Battery Pack (LB-4A), Multi Box (MB-4A), Status Indicator (SI-4A), Wiring Cable (WC-4A), PC Connection Cable (CP-4A), Ready Indicator (RI-3A)	Docking Station (DS-4A), Battery Charger (BC-1A), Battery Pack (LB-4A), Multi Box (MB-4A), Status Indicator (SI-4A), Wiring Cable (WC-4A), PC Connection Cable (CP-4A), Ready Indicator (RI-3A), X-ray Interface Box (XB-1A)	MODIFIED
Software	CXDI Control Software V3.10	CXDI Control Software V2.16	CXDI Control Software V2.19	MODIFIED
Photographing Mode	Standard Synchronization Mode, Non Generator Connection Mode	Standard Synchronization Mode, Non Generator Connection Mode, Standalone Mode	Standard Synchronization Mode, Non Generator Connection Mode	MODIFIED
Wireless Communication	IEEE 802.11n/ac/a/g/b 2.4GHz/5GHz Bluetooth Low Energy	IEEE 802.11n 2.4GHz/5GHz	IEEE 802.11n/a/g/b 2.4GHz/5GHz	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 an update to the software in the CXDI-710C, changes to the optional accessories, change in case material from fiberglass to magnesium alloy, addition of Bluetooth, and removal of Standalone mode.

Evaluation of the changes to the CXDI-710C 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.