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

January 26, 2021

Re: K203849
Trade/Device Name: Digital Radiography CXDI-CS01
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: December 30, 2020
Received: December 31, 2020

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)*

K203849

Device Name
DIGITAL RADIOGRAPHY CXDI-CS01

Indications for Use *(Describe)*

The DIGITAL RADIOGRAPHY CXDI-CS01 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

K203849

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:	12/30/2020	
Submission Type:	Special 510(k) Submission	
Proposed Device:	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-CS01
	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:	K192632
	Manufacturer:	Canon, Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-702C Wireless, CXDI-402C Wireless
	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
Reference Devices:	510k Number:	K171270
	Manufacturer:	Canon, Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-410C Wireless
	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
	510k Number:	K170332
	Manufacturer:	Canon, Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-810C Wireless, CXDI-710C Wireless
	Common Name:	Solid State X-ray Imager
	Classification Name:	Stationary X-ray System
	Classification:	892.1680, Stationary X-ray System

Product Code: MQB

Device Description: The *DIGITAL RADIOGRAPHY CXDI-CS01* is a series of solid-state x-ray detectors. 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 digital values are sent to the PC via wired or wireless connection, converted to images with the CXDI Control Software (CCS), then displayed on monitors. The digital value can be communicated to the operator console via wired or wireless connection.

The subject of this Special 510(k) submission is a change to the DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C Wireless to make a series of detectors including the DIGITAL RADIOGRAPHY CXDI-702C Wireless (K192632), CXDI-402C Wireless (K192632), CXDI-710C Wireless (K170332), CXDI-810C Wireless (K170332), and CXDI-410C Wireless (K171270), under the proposed device the *DIGITAL RADIOGRAPHY CXDI-CS01*. This change will change the Multi Box to be a Standard Component from an optional component for the detectors. The Multi Box has the functions of connecting to the X-ray generator to synchronize the X-ray exposure and photographing, supplying power to the FPD (front panel detector), communicating between the FPD and the image capture computer, connecting the status indicator to the Multi Box to turn the FPD on and off and switch to a ready state, connecting to the WLAN access point to communicate to the FPD wirelessly, and connecting to the docking station to charge the FPD and communicate between the FPD and image capture computer. These functions of the Multi Box have not changed since its clearance under the predicate device (K192632). The X-ray I/F (Interface) Unit has been removed as an optional component for the DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C Wireless as the Multi Box performs the function of the X-ray I/F Unit (connecting to the X-ray generator to synchronize the x-ray exposure and photographing). In addition, the detectors will all use the version software cleared under the DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C Wireless (K192632). Together, these changes make up the *DIGITAL RADIOGRAPHY CXDI-CS01*.

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-CS01* 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:

Comparisons with the predicate devices show the characteristics of the proposed modifications (making the Multi Box a standard component, removing the X-ray I/F Interface as an option, and updating the CXDI Control Software to version 2.19) to the *DIGITAL RADIOGRAPHY CXDI-CS01* to be substantially equivalent to the predicate device.

	Proposed Device	**Predicate Device**	**Reference Devices**	
Trade Name	CXDI-CS01	CXDI-702C Wireless / CXDI-402C Wireless	CXDI-710C Wireless / CXDI-810C Wireless / CXDI-410C Wireless	
510(k) Submitter [Number]	Canon, Inc. [TBD]	Canon, Inc. [K192632]	Canon, Inc. [K170332] [K171270]	IDENTICAL
Indication for Use	The DIGITAL RADIOGRAPHY CXDI-CS01 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-402C Wireless and 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.	The DIGITAL RADIOGRAPHY CXDI-710C Wireless, DIGITAL RADIOGRAPHY CXDI-810C Wireless, and DIGITAL RADIOGRAPHY CXDI-410C 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	[Detector of CXDI-702C Wireless and CXDI-402C Wireless] Magnesium alloy [Detector of CXDI-710C Wireless, CXDI-810C Wireless and CXDI-410C Wireless] Carbon Fiber	Magnesium alloy	Carbon Fiber	IDENTICAL
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	125µm	125µm	125µm	IDENTICAL
Spatial Resolution	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]	IDENTICAL

	Proposed Device	Predicate Device	Reference Devices	
Trade Name	CXDI-CS01	CXDI-702C Wireless / CXDI-402C Wireless	CXDI-710C Wireless / CXDI-810C Wireless / CXDI-410C Wireless	
IP Level	[Detector of CXDI-702C Wireless and CXDI-402C Wireless] IP54 [Detector of CXDI-710C Wireless, CXDI-810C Wireless and CXDI-410C Wireless] IPX7	IP54	IPX7	IDENTICAL
Standard Components	Detectors (Sensors), Battery Pack, Documentation (Manuals), Multi Box	Detector (Sensor), Battery Pack, Documentation (Manuals)	Detector (Sensor), Battery Pack, Documentation (Manuals)	MODIFIED
Options	Docking Station, Battery Charger, Battery Pack, Status Indicator, Wiring Cable, PC Connection Cable, Ready Indicator	Docking Station, Battery Charger, Battery Pack, Multi Box, Status Indicator, Wiring Cable, PC Connection Cable, Ready Indicator, X-ray I/F unit	Docking Station, Battery Charger, Battery Pack, Multi Box, Status Indicator, Wiring Cable, PC Connection Cable, Ready Indicator	MODIFIED
Software	CXDI Control Software V2.19	CXDI Control Software V2.19	CXDI Control Software V2.16	MODIFIED
Photographing Mode	[Detector of CXDI-702C Wireless and CXDI-402C Wireless] Standard Synchronization Mode, Non Generator Connection Mode [Detector of CXDI-710C Wireless, CXDI-810C Wireless and CXDI-410C Wireless] Standard Synchronization Mode, Non Generator Connection Mode, Standalone Mode	Standard Synchronization Mode, Non Generator Connection Mode	Standard Synchronization Mode, Non Generator Connection Mode, Standalone Mode	IDENTICAL

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. Before using the product, be sure to read the manual thoroughly in order to utilize it more effectively.

Performance: The fundamental scientific technology of the detectors under *DIGITAL RADIOGRAPHY CXDI-CS01* have not been modified. The detector units of the *DIGITAL RADIOGRAPHY CXDI-CS01* has not been modified, and the change is to update the software in the DIGITAL RADIOGRAPHY CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless; make the Multi Box a standard component; and remove the X-ray I/F Unit as an optional component.

Documentation was provided demonstrating that the changes to DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C Wireless do not impact the device's compliance with FDA requirements stated in "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices".

Evaluation of the changes to the *DIGITAL RADIOGRAPHY CXDI-CS01* confirmed that the changes did not impact *DIGITAL RADIOGRAPHY CXDI-CS01* 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, 60601-1-3, 60601-1-6, 62366, 60601-2-54, 62220-1, and 62304.

These verification/validation activities successfully demonstrated that the device continues to meet the standards for the areas impacted by the device 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 conducted supports a determination of substantial equivalence for the *DIGITAL RADIOGRAPHY CXDI-CS01* device.

Conclusion: Canon Inc. considers the *DIGITAL RADIOGRAPHY CXDI-CS01* 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.