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

November 7, 2019

Re: K192632
Trade/Device Name: DIGITAL RADIOGRAPHY CXDI-702C Wireless
DIGITAL RADIOGRAPHY CXDI-402C Wireless
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: November 6, 2019
Received: November 7, 2019

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192632

Device Name
DIGITAL RADIOGRAPHY CXDI-702C Wireless
DIGITAL RADIOGRAPHY CXDI-402C Wireless

Indications for Use *(Describe)*
The DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C 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.

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. Tatsuya Yamazaki
General Manager
TEL: 81-3-3758-2111;
FAX: 81-3-5482-3960
yamazaki.tatsuya@mail.canon

Date Prepared: September 20, 2019

Submission Type: Special 510(k) Submission

Proposed Devices:	510(k) Number:	K192632
	Manufacturer:	Canon, Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-702C Wireless DIGITAL RADIOGRAPHY CXDI-402C Wireless
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Stationary X-ray system
	Product Code:	MQB
	Regulatory Standard:	892.1680 (Stationary X-ray System)
Predicate Device:	Manufacturer:	Canon, Inc.
	510(k) Number:	K170332
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-710C Wireless
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Stationary X-ray system
	Product Code:	MQB
	Regulatory Standard:	892.1680 (Stationary X-ray System)
Reference Device:	Manufacturer:	Canon, Inc.
	510(k) Number:	K171270
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-410C Wireless
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Stationary X-ray system
	Product Code:	MQB
	Regulatory Standard:	892.1680 (Stationary X-ray System)

Device Description: The CXDI-702C Wireless and CXDI-402C Wireless are solid-state x-ray imagers with approximate imaging areas of 350 x 426 mm and 415 x 426 mm, respectively. 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 wired or wireless connection.

The subject of this Special 510(k) submission is a change to the Digital Radiography CXDI-710C Wireless and CXDI-410C Wireless to add the X-ray I/F unit option, update to the CXDI control software, change the IP Level, make changes to the case, and remove Standalone mode. The X-Ray I/F unit synchronizes the timing of the X-ray irradiation with the detector's capture and has been included in other Canon devices (CXDI-701C Wireless (K131106)). The X-Ray I/F Unit is an optional unit that allows the proposed device work together with several older units that use the X-ray I/F Unit instead of the multibox. The IP Level was changed from IPX7 to IP54. The Standalone mode was removed from the proposed devices. The imaging process to

sharpen images, Edge Enhancement, was included in the Digital Radiography CXDI-710C Wireless and CXDI-410C Wireless, but adjustments of multiple imaging parameters were required to enhance structured edges. The optional feature, Advanced Edge Enhancement, for CXDI-702C Wireless and CXDI-402C Wireless automatically adjusts the six image processing parameters (Enhancement – Edge Enhancement, Enhancement – Edge Frequency, Enhancement – Contrast Boost, Dynamic Range Adjustment – Dark Region, Dynamic Range Enhancement – Bright Region, and Noise Reduction - Effect) by one button to enhance structures. The CXDI control software has been updated to a new version for functional improvements. The material of the casing of the detector has changed from fiberglass to magnesium alloy. Together, these changes to the Digital Radiography CXDI-710C Wireless and CXDI 410C Wireless make up the Digital Radiography CXDI-702C Wireless and CXDI-402C Wireless. The Digital Radiography CXDI-710C Wireless and CXDI-410C Wireless clearances are not impacted by this submission.

Indication for Use: The Indication for Use statement is identical to the predicate device with the exception of the device name. 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-702C Wireless and CXDI-402C 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.

Summary of Technological Characteristics: Comparisons with the predicate devices show the characteristics of the proposed modifications (addition of the X-Ray I/F unit option, the update to the CXDI control software, change in case material, and the removal of the Standalone mode) to the DIGITAL RADIOGRAPHY CXDI-710C Wireless and CXDI-410C Wireless to be substantially equivalent to the predicate device.

	Proposed Device		**Predicate Device**	**Reference Device**	
Trade Name	DIGITAL RADIOGRAPHY CXDI-702C Wireless	DIGITAL RADIOGRAPHY CXDI-402C Wireless	DIGITAL RADIOGRAPHY CXDI-710C Wireless	DIGITAL RADIOGRAPHY CXDI-410C Wireless	
510(k) Submitter [Number]	Canon, Inc. [K192632]		Canon, Inc. [K170332]	Canon, Inc. [K171270]	IDENTICAL
Indication for Use	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	The DIGITAL RADIOGRAPHY CXDI-402C 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	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	The 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	IDENTICAL

	mammography applications.	mammography applications.	mammography applications.	mammography applications.	
Application	General Radiography		General Radiography		IDENTICAL
Case Material	Magnesium alloy		Fiberglass		MODIFIED
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]		CsI(Tl) [Cesium Iodide doped with Thallium]		IDENTICAL
Pixel Pitch	125µm		125µm		IDENTICAL
Pixels	2,800 x 3,408 (≈ 9.5 mil)	3,408 x 3,320 (≈ 11.3 mil)	2,800 x 3,408 (≈ 9.5 mil)	3,408 x 3,320 (≈ 11.3 mil)	IDENTICAL
External Dimensions	384 x 460 x 15.7 mm	460 x 460 x 15.7 mm	384 x 460 x 15.7 mm	460 x 460 x 15.7 mm	IDENTICAL
Weight	≈ 3.1 kg	≈ 3.7 kg	≈ 2.3 kg	≈ 2.8 kg	MODIFIED
Attenuation Equivalent	Max. 0.40 mmAl	Max. 0.37 mmAl	Max. 0.21 mmAl		MODIFIED
Spatial Resolution	35% [MTF@2lp/mm]		35% [MTF@2lp/mm]		IDENTICAL
Control SW	CXDI Control Software V 2.19		CXDI Control Software V 2.16		MODIFIED
Wireless Functions	Communication between Detector and: Multi Box Control PC X-ray I/F Unit		Communication between Detector and: Multi Box Control PC		MODIFIED
IP Level	IP54		IPX7		MODIFIED
Photographing mode	Standard Synchronization Mode Non Generator Connection Mode		Standard Synchronization Mode Non Generator Connection Mode Standalone Mode		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. Before using the product, be sure to read the manual thoroughly in order to utilize it more effectively.

Summary of Non-Clinical / Test Data:

The fundamental scientific technology of the DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C Wireless has not been modified. 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.

Tests were performed on the models which demonstrated that the devices are safe and effective, perform comparably to the predicate devices, and are substantially equivalent to the predicate devices. Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken by the new device and the predicate devices, including the Advanced edge enhancement feature. Interviews were conducted with experienced clinicians on the usability of the advanced edge enhancement.

Documentation was provided demonstrating compliance of the CXDI-702C Wireless and CXDI-402C Wireless to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for a moderate LOC, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards.

Other FDA guidance documents used in development include Radio Frequency Wireless Technology in Medical Devices and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Documentation was provided demonstrating that the changes to CXDI-710C and CXDI-410C 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.

Testing confirmed that the CXDI-702C Wireless and CXDI-402C Wireless 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, 60601-1-6, and 60601-2-54.

Biocompatibility evaluation confirmed that the changes to CXDI-710C and CXDI-410C do not impact the devices' safety and that the CXDI-702C Wireless and CXDI-402C Wireless comply with ISO 10993-1, 10993-5, and 10993-10.

Together, 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 testing conducted supports a determination of substantial equivalence for the CXDI-702C Wireless and CXDI-402C Wireless devices.

Conclusion: *Canon, Inc.* considers the DIGITAL RADIOGRAPHY CXDI-702C Wireless and CXDI-402C Wireless to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.