September 27, 2022

Canon Inc.
% Saori Sawaki
Business Manager, Regulatory Consultant
Ken Block Consulting LLC
800 E Campbell Road, Suite 202
RICHARDSON TX 75081

Re: K222661
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: September 2, 2022
Received: September 2, 2022

Dear Saori Sawaki:

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, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*

K222661

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

K222661

Applicant/ Sponsor: Canon Inc.
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Contact Person: Mr. Akira Hirai
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Date Prepared: September 2, 2022

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
	Product Code:	MQB
	Regulation:	892.1680, Stationary X-ray System
Predicate Device:	Clearance:	K203849
	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
	Product Code:	MQB
	Regulation:	892.1680, Stationary X-ray System

Device Description:

The DIGITAL RADIOGRAPHY CXDI-CS01 (hereinafter referred to as CXDI-CS01) is a solid-state x-ray imager. The CXDI-CS01 is a series of detectors, and in the predicate device (K203849) consists of the CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless.

The CXDI-CS01 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. The digital values are sent to the PC via a wired or wireless connection, converted to images with the CXDI Control Software, and then displayed on the PC/monitors. The PC/monitors used with the CXDI-CS01 are not a part of this submission.

The subject of this Special 510(k) submission is a change to the CXDI-CS01 to add the DIGITAL RADIOGRAPHY CXDI-Pro (hereinafter referred to as CXDI-Pro) series and the DIGITAL RADIOGRAPHY CXDI-Elite (hereinafter referred to as CXDI-Elite) series detectors to the CXDI-CS01 series of detectors. In addition, the CXDI-Pro and CXDI-Elite components and features (Bluetooth connection and the Built-in AEC Assistance) have been added to the CXDI-CS01. The CXDI Control Software has been updated from V2.19.0.7 to V3.10.2.2 to add the Intelligent NR function (cleared under K212269), update the GPU driver, add several minor functional changes, and fix bugs. Together, these changes make up the CXDI-CS01.

Indications 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.

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510(k) SUMMARY

Summary of Technological Characteristics:

Comparison with the predicate device shows the technological characteristics of the proposed CXDI-CS01 is substantially equivalent to the predicate device.

The major differences between the proposed CXDI-CS01 and the predicate are differences in the components and a newer version of the CXDI control software. The proposed indications for use statement is identical to the indications for use statement of the predicate device.

	Proposed Device	Predicate Device	
Trade Name	DIGITAL RADIOGRAPHY CXDI-CS01	DIGITAL RADIOGRAPHY CXDI-CS01	
510(k) Submitter [Number]	Canon Inc. [TBD]	Canon Inc. [K203849]	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-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.	IDENTICAL
Application	General Radiography	General Radiography	IDENTICAL
Software	CXDI Control Software V3.10	CXDI Control Software V2.19	MODIFIED
Components	Detectors Battery Pack (LB-4A) Battery Charger (BC-1A/BC-01) Multi Box (MB-4A/MB-02) Power Box (PB-01) Ready Indicator (RI-3A) Status Indicator (SI-4A/SI-01) Wiring Cable (WC-4A/WC-01) PC Connection Cable (CP-4A/CP-01) Docking Station (DS-4A) Detector Stand (DS-01)	Detectors Battery Pack (LB-4A) Battery Charger (BC-1A) Multi Box (MB-4A) Ready Indicator (RI-3A) Status Indicator (SI-4A) Wiring Cable (WC-4A) PC Connection Cable (CP-4A) Docking Station (DS-4A)	MODIFIED
Detector	CXDI-702C Wireless CXDI-402C Wireless CXDI-710C Wireless CXDI-810C Wireless CXDI-410C Wireless CXDI-Pro: CXDI-703C Wireless CXDI-403C Wireless CXDI-Elite: CXDI-720C Wireless	CXDI-702C Wireless CXDI-402C Wireless CXDI-710C Wireless CXDI-810C Wireless CXDI-410C Wireless	MODIFIED
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]	IDENTICAL
Pixel Pitch	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, CXDI-410C Wireless, and CXDI-Elite: 125µm CXDI-Pro: 140 µm	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, CXDI-410C Wireless: 125µm	MODIFIED
Spatial Resolution	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: 35% [MTF@2lp/mm] CXDI-Pro and CXDI-Elite: 45% [MTF@2lp/mm]	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, CXDI-410C Wireless: 35% [MTF@2lp/mm]	MODIFIED

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510(k) SUMMARY

	Proposed Device	Predicate Device	
Trade Name	DIGITAL RADIOGRAPHY CXDI-CS01	DIGITAL RADIOGRAPHY CXDI-CS01	
510(k) Submitter [Number]	Canon Inc. [TBD]	Canon Inc. [K203849]	IDENTICAL
DQE	CXDI-702C Wireless: 58% [@0.5 lp/mm, 1 mR] CXDI-402C Wireless: 58% [@0.5 lp/mm, 3.5 uGy] CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: 60% [@0 lp/mm, 4 uGy] CXDI-Pro: 58% [@0.5 lp/mm, 3.5 uGy] CXDI-Elite: 67% [@0.5 lp/mm, 3.5 uGy]	CXDI-702C Wireless: 58% [@0.5 lp/mm, 1 mR] CXDI-402C Wireless: 58% [@0.5 lp/mm, 3.5 uGy] CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: 60% [@0 lp/mm, 4 uGy]	MODIFIED
IP Level	CXDI-702C Wireless and CXDI-402C Wireless IP54 CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless IPX7 CXDI-Pro: IP55 CXDI-Elite: IP57	CXDI-702C Wireless and CXDI-402C Wireless IP54 CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless IPX7	MODIFIED
Wireless Communication	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: IEEE 802.11n 2.4GHz/5GHz CXDI-Pro and CXDI-Elite: IEEE 802.11a/b/g/n/ac 2.4GHz/5GHz Bluetooth Low Energy	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: IEEE 802.11n 2.4GHz/5GHz	MODIFIED
Photographing Mode	CXDI-702C Wireless, CXDI-402C Wireless, and CXDI-Pro: Standard Synchronization Mode and Non Generator Connection Mode CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: Standard Synchronization Mode, Non Generator Connection Mode, and Standalone Mode CXDI-Elite: Standard Synchronization Mode, Standard Synchronization Mode with Built in AEC Assistance, Non Generator Connection Mode, and Standalone Mode	CXDI-702C Wireless and CXDI-402C Wireless: Standard Synchronization Mode and Non Generator Connection Mode CXDI-710C Wireless, CXDI-810C Wireless, and CXDI-410C Wireless: Standard Synchronization Mode, Non Generator Connection Mode, and Standalone Mode	MODIFIED

Summary of Non-Clinical / Test Data:

The fundamental scientific technology of the CXDI-CS01 has not been modified. The change is the addition of the CXDI-Pro series and the CXDI-Elite series detectors and components.

Evaluation of the addition of the new detectors confirmed that the change did not impact 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, 60601-2-54, 62220-1, 62304, and 62366.

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. Clinical testing is not necessary for the current submission, based on the minor differences from the predicate device. Adequate detector bench testing should be sufficient to demonstrate that the subject detector CXDI-CS01 works as intended. Therefore, the verification/validation activities conducted support a determination of substantial equivalence for the CXDI-CS01.

The proposed device follows the applicable elements of the following FDA guidance documents: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Radio Frequency Wireless Technology in Medical Devices*, and *Pediatric Information for X-ray Imaging Device Premarket Notifications*.

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