January 24, 2022

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

Re: K213780
Trade/Device Name: DIGITAL RADIOGRAPHY CXDI-Elite, DIGITAL RADIOGRAPHY E1
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: December 2, 2021
Received: December 3, 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 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)*
K213780

Device Name
DIGITAL RADIOGRAPHY CXDI-Elite
DIGITAL RADIOGRAPHY E1

Indications for Use *(Describe)*
The DIGITAL RADIOGRAPHY CXDI-Elite / E1 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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5. 510(k) SUMMARY

K213780

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:	December 2, 2021	
Proposed Device	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-Elite DIGITAL RADIOGRAPHY E1
	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:	K170332
	Manufacturer:	Canon Inc.
	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
	Regulation:	892.1680, Stationary X-ray System
Reference Device:	Clearance:	K192632
	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-702C Wireless
	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-Elite, also called the DIGITAL RADIOGRAPHY E1, (hereinafter referred to as CXDI-Elite) is a solid-state x-ray imager using TFT (thin-film transistor) arrays. The CXDI-Elite is a series of detectors, currently consisting of the CXDI-720C Wireless detector unit, also called the AR-E3543W detector. The detector intercepts x-ray photons, and the Cesium-Iodide 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 a digital image, 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 monitors used with the CXDI-Elite are not a part of this submission.

The CXDI Control Software is updated from V2.16 to V3.10 in this submission. The update to the software includes bug fixes, modification to check-in function,

modification to communication with X-ray emission devise, calibration support, addition of the Intelligent NR function (previously cleared under K212269), and the addition of Standard Synchronization Mode with Built in AEC Assistance.

Indications for Use:

The DIGITAL RADIOGRAPHY CXDI-Elite / E1 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 technological characteristics of the CXDI-Elite is substantially equivalent to the predicate device. The flat panel detector units are functionally similar, but the proposed device adds Standard Synchronization Mode with Built in AEC Assistance as a photographing mode.

The major differences between the CXDI-Elite and the predicate are differences in standard and optional components, newer version of CXDI control software, difference in case material, and a photographing mode not available in the predicate device. The proposed indications for use statement is identical to the predicate device.

	Proposed Device	Predicate Device	Reference Devices	
Trade Name	DIGITAL RADIOGRAPHY CXDI-Elite / E1	DIGITAL RADIOGRAPHY CXDI-710C Wireless	DIGITAL RADIOGRAPHY CXDI-702C Wireless	
510(k) Submitter [Number]	Canon Inc. [K213780]	Canon Inc. [K170332]	Canon Inc. [K192632]	IDENTICAL
Indication for Use	The DIGITAL RADIOGRAPHY CXDI-Elite / E1 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	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	125µm	125µm	125µm	IDENTICAL
Spatial Resolution	45% [MTF@2lp/mm]	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]	IDENTICAL
IP Level	IP57	IPX7	IP54	MODIFIED

5. 510(k) SUMMARY

K213780

Components	Detector (Sensor) Battery Pack (LB-4A) Battery Charger (BC-01/BC-1A) Multi Box (MB-02) Status Indicator (SI-01/SI-4A) Wiring Cable (WC-01) PC Connection Cable (CP-01) Ready Indicator (RI-3A) X-ray Interface Box (XB-1A)	Detector (Sensor) Battery Pack (LB-4A) Battery Charger (BC-1A) 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)	Detector (Sensor) Battery Pack (LB-4A) Battery Charger (BC-1A) 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) Docking Station (DS-4A)	MODIFIED
Software	CXDI Control Software V3.10	CXDI Control Software V2.16	CXDI Control Software V2.19	MODIFIED
External Dimensions	384 x 460 x 15.5 mm	384 x 460 x 15.7 mm	384 x 460 x 15.7 mm	MODIFIED
DQE	A typical DQE value at 3.5uGy in 0.5 lp/mm is 0.67, with measurement error of less than ±10%.	A typical DQE value at 4 µGy in 0 lp/mm is 0.6. The level of uncertainty is estimated as less than ±10%.	A typical DQE value at 1 mR in 0.5 lp/mm is 0.58. The level of uncertainty is estimated as less than ±10%.	MODIFIED
Detector Technology	TFT	TFT	TFT	IDENTICAL
Photographing Mode	Standard Synchronization Mode, Standard Synchronization Mode with Built in AEC Assistance, Non Generator Connection Mode, Standalone Mode	Standard Synchronization Mode, Non Generator Connection Mode, Standalone Mode	Standard Synchronization Mode, Non Generator Connection Mode	MODIFIED
Wireless Communication	IEEE 802.11a/b/g/n/ac 2.4GHz/5GHz Bluetooth Low Energy	IEEE 802.11n 2.4GHz/5GHz	IEEE 802.11n/a/g/b 2.4GHz/5GHz	MODIFIED

Summary of Non-Clinical / Test Data:

Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons. Documentation was provided demonstrating compliance of the *CXDI-Elite* to all FDA requirements stated in *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, 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 *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

Documentation was provided demonstrating that the device complies with the FDA requirements stated in *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*. The evaluations of the device, compared to the predicate, show the device to be equivalent to the predicate.

Testing confirmed that the device complies 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, and 60601-2-54. An IP Code of IP57 has been established for the CXDI-Elite per IEC 60529.

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-Elite / E1 works as intended.

Together, these verification/validation activities successfully demonstrated that the device correctly performs as designed, has been validated for its intended use, 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 device.

Conclusion: Company considers the DIGITAL RADIOGRAPHY CXDI-Elite / E1 device 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.