April 26, 2024

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

Re: K232298
Trade/Device Name: DIGITAL RADIOGRAPHY CXDI-RF Wireless Bl
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, MQB
Dated: March 26, 2024
Received: March 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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)*
K232298

Device Name
DIGITAL RADIOGRAPHY CXDI-RF Wireless B1

Indications for Use *(Describe)*
DIGITAL RADIOGRAPHY CXDI-RF Wireless B1 is indicated for use in generating radiographic images of human anatomy to replace the radiographic film/screen systems in all general purpose diagnostic procedures. It is also used for generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers.
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 **K232298**

Applicant/ Sponsor:	Canon Inc. 9-1 Imaikami-cho Nakahara-ku, Kanagawa 211-8501 JAPAN	
Contact Person:	Mr. Shigeo Watanabe General Manager TEL: 81-3-3758-2111 FAX: 81-44-739-6695 watanabe.shigeo@mail.canon	
Date Prepared:	March 26, 2024	
Subject Device	Manufacturer:	Canon Inc.
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Product Code:	OWB
	Subsequent Product Codes:	MQB
	Regulation:	21 CFR 892.1650, Image-intensified fluoroscopic x-ray system
	Class:	II
Predicate Device:	Clearance:	K171194, 05/24/2017
	Manufacturer:	Canon Inc.
	Trade Name:	AS-10/CXDI-401RF
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Product Code:	OWB
	Subsequent Product Codes:	MQB, JAA
	Regulation:	21 CFR 892.1650, Image-intensified fluoroscopic x-ray system
	Class:	II
Device Description:	The proposed CXDI-RF Wireless B1 is a solid state X-ray imager, which is capable of both fluoroscopic and spot radiographic imaging and has a common Thallium-doped Cesium Iodide (CsI:TI) scintillator. The CXDI-RF Wireless B1 will be integrated as a component into the Canon fluoroscopy x-ray system for fluoroscopic and radiographic imaging. The CXDI-RF Wireless B1 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 (CXDI Controller RF version 3.11), and then displayed on the PC/monitors. The PC/monitors used with the CXDI-RF Wireless B1 are not a part of this submission.	
Indications for Use:	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1 is indicated for use in generating radiographic images of human anatomy to replace the radiographic film/screen systems in all general purpose diagnostic procedures. It is also used for	

generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers.
Not intended for mammography applications.

Summary of Technological Characteristics:

Comparison with the predicate device shows the technological characteristics of the proposed CXDI-RF Wireless B1 are substantially equivalent to the predicate device. The proposed indications for use statement differs slightly in wording from the predicates but does not impact the intended use. Both the proposed and predicate devices are indicated for fluoroscopic and radiographic use. The major differences between the proposed CXDI-RF Wireless B1 and the predicate are differences in the components, the new control software, the new photographing modes, wireless communication, and the decrease in size resulting in less pixels, weight, smaller image area, etc. Those changes were evaluated and verified/validated to support the substantial equivalence and demonstrate these differences raise no new different questions of safety and effectiveness.

	New Device	Predicate Device
Trade Name	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1	AS-10/CXDI-401RF
510(k) Submitter [Number]	Canon Inc. [K232298]	Canon Inc. [K171194]
Indications for Use	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1 is indicated for use in generating radiographic images of human anatomy to replace the radiographic film/screen systems in all general purpose diagnostic procedures. It is also used for generating fluoroscopic images, when integrated into the X-ray diagnostic systems, to replace the spot-film devices and the X-ray image intensifiers. Not intended for mammography applications.	The AS-10 / CXDI-401RF is indicated for use in generating fluoroscopic and radiographic images of human anatomy for angiography, diagnostic, and interventional procedures. The device is intended to replace spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.
Application	Fluoroscopy and General Radiology	Fluoroscopy and General Radiology
Software	CXDI Control Software RF V3.11	CXDI Control Software V2
Standard Components	Detector (Sensor) Unit (AF-B4343W) Multi Box (MB-01) Battery Pack (LB-4A)	Detector (Sensor) Unit (AS-10 / CXDI-401RF) Power Box (PB-9) Optical Cable (BH7-9753-000, BH7-9754-020) Power Supply Cable (BH7-9923-000, BH7-9924-000)
Optional Components	Battery Charger (BC-01, BC-1A) Status Indicator (SI-01) Ready Indicator (RI-3A) Wiring Cable (WC-01) XIF Expansion Unit for Radiography (IFU-MB01-XIF) Expansion Unit for AF-B4343W (IFU-MB01) Expansion Unit for CXDI-710/702 Series (IFU-MB01-S)	Grid Unit
Detector Technology	Scintillator and amorphous silicon (a-Si)	Scintillator and amorphous silicon (a-Si)
Scintillator	Cesium Iodide doped with Thallium (CsI(Tl))	Cesium Iodide doped with Thallium (CsI(Tl))
External Dimensions	460 x 460 x 15.5 mm	469 x 469 x 58 mm
Weight	3.5 ± 0.1 kg (with Battery)	13 kg (Sensor Unit without Cable)

	New Device	Predicate Device
Trade Name	DIGITAL RADIOGRAPHY CXDI-RF Wireless B1	AS-10/CXDI-401RF
Pixel Pitch	160 x 160 µm	160 x 160 µm
Dynamic Range	Fluoroscopy: 0.02 to 1.9 uGy Radiography: 0.05 to 25 uG	Fluoroscopy: 0.01 to 1.9 µGy Radiography: 0.05 to 25 µGy
Spatial Resolution	RQA5 =0.38 (MTF@2lp/mm)	RQA5 =0.28 (MTF@2lp/mm)
DQE	0.67 (@ 2 µGy in 0lp/mm)	0.75 (@ 1 µGy in 0lp/mm)
Pixels	2,656 x 2,592 (Approximately 6.8 million)	2,688 x 2,688 (Approximately 7.2 million)
Imaging Area (Detector)	415 x 425 mm	430 mm x 430 mm
Attenuation Equivalent	Max 0.26 mmAl	0.30 mmAl
Binning Mode	1x1, 2x2, 3x3	1x1, 2x2, 3x3
Acquisition Mode	Radiography: Up to 15 fps Fluoroscopy : Up to 30 fps	Radiography: Up to 15 fps Fluoroscopy : Up to 30 fps
Cooling	Active air cooling In tray	Active air cooling
Image Processing	Preprocessing	Preprocessing
A/D Conversion	16-bit	16-bit
Grayscale	65536 grayscales (16-bit)	65536 grayscales (16-bit)
Photographing Mode	Standard Synchronization Mode, Standard Synchronization Mode with Built in AEC Assistance	Generator Connection Mode, Non-Generator Connection Mode
Wireless Communication	IEEE802.11a/b/g/n (2.4 GHz/5GHz)	N/A
Sensor Element Spacing	160 µm	160 µm
Fill Factor	89 %	85 %
Total Element Count	2,656 x 2,592	2,688 x 2,688

Summary of Non-Clinical/ Test Data:

The CXDI-RF Wireless B1 was developed and produced under consideration of all applicable technical standards, internal specifications, and FDA guidance documents.

The CXDI-RF Wireless B1 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,*
- *Content of Premarket Submissions for Device Software Functions,*
- *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.*

Tests, including verification/validation, were performed on the CXDI-RF Wireless B1 according to the following FDA recognized concensus standards:

- ISO 10993-1: 2018, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5: 2009, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10:2010, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
- ISO 10993-12: 2012, *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*
- ISO 14971: 2019, *Medical devices - Application of risk management to medical devices*
- IEC 62304: 2015, *Medical device software - Software life cycle processes*
- IEC 62366-1: 2020, *Medical devices - Part 1: Application of usability engineering to medical devices*
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)*
- IEC 60601-1-2 Edition 4.0 2014-02, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- IEC 60601-1-3 Edition 2.1 2013-04, *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment*
- IEC 60601-1-6 Edition 3.1 2013-10, *Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability*
- IEC 60601-2-54: 2018, *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

The tests successfully demonstrated that the differences from the predicate device raise no new questions regarding either safety or effectiveness and supports a determination of substantial equivalence for the CXDI-RF Wireless B1.

Clinical Testing: No clinical testing was required as non-clinical testing should be sufficient to demonstrate that the DIGITAL RADIOGRAPHY CXDI-RF Wireless B1 works as intended.

Conclusion: Canon Inc. considers the DIGITAL RADIOGRAPHY CXDI-RF Wireless B1 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.