Canon, Inc. – Medical Equipment Group
% Ms. Diane Rutherford
Submissions Manager
Ken Block Consulting
1201 Richardson Drive, Suite 160
RICHARDSON TX 75080

November 17, 2017

Re: K171270
Trade/Device Name: DIGITAL RADIOGRAPHY CXDI-410C Wireless
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 26, 2017
Received: October 27, 2017

Dear Ms. Rutherford:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171270

Device Name
DIGITAL RADIOGRAPHY CXDI-410C Wireless

Indications for Use *(Describe)*
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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) SUMMARY

Submitter:	Canon, Inc. – Medical Equipment Group 9-1, Imaikami-cho, Nakahara-ku Kawasaki, Kanagawa 211-8501 Japan	
Contact Person:	Canon, Inc. – Medical Equipment Group Mr. Shinji Mori Manager 9-1, Imaikami-cho, Nakahara-ku Kawasaki, Kanagawa 211-8501, Japan TEL: 81-3-3758-2111 FAX: 81-44-739-6493 mori.shinji@canon.co.jp	
Date Prepared:	April 26, 2017	
Proposed Device	Manufacturer:	Canon, Inc. – Medical Equipment Group
	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
Predicate Device:	Clearance:	K133693 dated July 01, 2014
	Manufacturer:	Canon, Inc. – Medical Equipment Group
	Trade Name:	DIGITAL RADIOGRAPHY CXDI-401C 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-410C Wireless is a solid state x-ray imager with an approximate imaging area of 42.6 x 41.5 cm. The detector intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo-detectors 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 wiring connection or wireless.

For the proposed model, temporary image storage is now possible and the detector weigh has been reduced from that of the predicate. The proposed model has increased protection against ingress, and continues to include the Standard Synchronization Mode, Non-Generator Connection Mode (detection of x-ray irradiation without direct electrical connection to the x-ray generator), and is compatible with the Scatter Correction feature. Testing has been conducted and has demonstrated that these changes have no impact on the safety or effectiveness of this flat panel detector.

The Standalone Mode allows for examinations using only the detector and a mobile X-ray system without a control computer by utilizing the temporary image storage on the FPD. The CXDI-410C Wireless can be used in emergency/trauma situations and other environments where equipment other than the detector and mobile X-ray system cannot be used and/or wireless communication is not possible.

The weight of the CXDI-410C (2.8kg) is effectively 25% less than the weight of the predicate CXDI-401C (3.8kg.) The weight reduction was accomplished through material changes, changes in the structure, and downsized components such as electrical boards and batteries.

The proposed device CXDI-410C offers an optional docking station. This option allows for a simplified method for charging the internal battery of the proposed CXDI-410C. The Docking Station connects to the PC with an Ethernet cable (cannot communicate wirelessly.) By placing a FPD into the docking station, that FPD is "registered" and available for use.

Statement of Intended Use:

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 mammography applications.

Summary of Technological Characteristics:

Comparisons with the predicate device show the technological characteristics of the proposed DIGITAL RADIOGRAPHY CXDI-410C Wireless device to be substantially equivalent to the predicate device. The proposed device is functionally identical to the predicate device.

The major difference between the proposed and predicate devices is that the proposed device has a reduction in weight, and can save captured in an internal nonvolatile memory of the detector. No other technological changes have been made to the proposed device.

	New Device: K17 CXDI-410C Wireless	**Predicate Device: K133693 CXDI-401C Wireless**
Indication for Use	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 mammography applications.	The DIGITAL RADIOGRAPHY CXDI-401C Wireless provides digital image capture for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.
Application	General Radiography	General Radiography
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]
Pixel Pitch	125 µm	125µm
Pixels	3,408 x 3,320 (≈ 11.3 mil)	3,408 x 3,320 (≈ 11.3 mil)
External Dimensions	460 x 460 x 15.7 mm	460 x 460 x 15.4 mm
Weight	≈ 2.8 kg	≈ 3.8 kg
DQE	0.6	0.6
Spatial Resolution	35% [MTF@2lp/mm]	35% [MTF@2lp/mm]
Control SW	CXDI Control Software Added Standalone function	CXDI Control Software
Device FW	PCA-FE-710 Added Standalone function Added wireless channels with DFS and TPC functions	PCA-FE-701

Wireless Functions	Communication between Detector and: Multi Box Control PC	Communication between Detector and: X-ray I/F Unit Control PC

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:

Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to the predicate device, and is substantially equivalent to the predicate device. Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display static and dynamic images taken with the new device and the predicate device. Documentation was provided demonstrating compliance of the CXDI-410C Wireless 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 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 CXDI-410C Wireless 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 CXDI-410C Wireless, compared to the predicate, show the CXDI-410C Wireless to be equivalent to the predicate.

Testing confirmed that the CXDI-410C Wireless 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, 60601-1-6, and 60601-2-54.

Together, these verification/validation activities successfully demonstrated that the CXDI-410C Wireless 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 CXDI-410C Wireless device.

Conclusion:

Canon, Inc. – Medical Equipment Group considers the DIGITAL RADIOGRAPHY CXDI-410C Wireless 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.