JUL 0 1 2014

K133693

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Canon

5. 510(k) SUMMARY

Submitter:	Canon, Inc. – Medical Equipment Group 30-2 Shimomaruko, 3-chrome Ohta-ku, Tokyo 146-8501 Japan
Contact Person:	*Applicant:* Mr. Shinji Mori Manager TEL: 81-3-3758-2111 FAX: 81-3-5482-3960 mori.shinji@canon.co.jp
Date Prepared:	November 22, 2013 *(revised Jan 9, 2014)*
Trade Name:	DIGITAL RADIOGRAPHY CXDI-401C Wireless
Common Name:	Flat Panel Digital Imager
Classification Name:	MQB (Solid State X-Ray Imager, Flat Panel/Digital Imager) 892.1680 (Stationary X-Ray System)
Predicate Devices:	K131106 MQB DIGITAL RADIOGRAPHY CXDI-701C Wireless, Canon, Inc. K103591 MQB DIGITAL RADIOGRAPHY CXDI-401C COMPACT, Canon, Inc.
Device Description:	The model of detector included in this submission is a solid state x-ray imager. Model *CXDI-401C Wireless* has an approximate imaging area of 41.5 x 42.6 cm. For this model, 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. The proposed model includes the Non-Generator Connection Mode, allowing this model to detect x-ray irradiation without direct electrical connection to the x-ray generator.
Statement of Intended Use:	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.
Summary of Technological Characteristics:	Comparisons with the predicate devices show the technological characteristics of the proposed DIGITAL RADIOGRAPHY CXDI-401C Wireless device to be substantially equivalent to the predicate devices. The proposed device is functionally identical to the predicate devices. The CXDI-401C Wireless is a modification of the CXDI-401C COMPACT cleared under K103591. The differences between the CXDI-401C Wireless and the CXDI-401C COMPACT are dynamic range, wireless capability, power supply, and external dimensions. However, for each of these features where the CXDI-401C Wireless differs from the CXDI-401C COMPACT, the CXDI-401C Wireless is identical to the CXDI-701C Wireless.

5. 510(k) SUMMARY (continued)

Summary of Technological Characteristics: (continued)

The CXDI-401C Wireless utilizes a flat panel detector (Scintillator [CsI] and amorphous silicon [a-Si]) [identical to both K131106 and K103591] with a pixel pitch of 125x125um [identical to both K131106 and K103591], 3,320 x 3,408 pixels [identical to K103591], external dimensions of 460 x 460 x 15.4mm [equivalent to K103591], a 16bit dynamic range [identical to K131106], wireless capability [identical to K131106], an approximate weight of 3.8kg [equivalent to K131106], and has both AC and DC power supply [identical to K131106]. The CXDI-401C Wireless can only be used with systems running Canon CXDI Control NE software.

Summary of Non-Clinical / Test Data:

Tests were performed on the proposed model which demonstrated that the device is safe and effective, performs comparably to the predicate device(s), and is substantially equivalent to the predicate device(s). Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken with the new device and the predicate devices. Documentation was provided demonstrating compliance of the CXDI-401C 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.

Documentation was provided demonstrating that the CXDI-401C Wireless RF technology is in accordance with the FDA Guidance Radio Frequency Wireless Technology in Medical Devices.

Documentation was provided demonstrating that the CXDI-401C 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 Non-clinical and Clinical Considerations of the CXDI-701C Wireless compared to the CXDI-401C Wireless, including the image quality evaluation, show the CXDI-401C Wireless to be equivalent to the CXDI-701C Wireless.

Testing confirmed that the CXDI-401C 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, 60601-1-3, and 60601-2-32.

Testing confirmed that the CXDI-401C Wireless complies with the FCC test standard for SAR, specifically 47CFR 2.1093 and for EMI test regulations FCC Part 15 Subpart B:2012 Class A and ICES-003 Issue 5:2012 Class A.

Together, these verification/validation activities successfully demonstrated that the CXDI-401C 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(s). Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the CXDI-401C Wireless device.

Conclusion:

Canon, Inc. – Medical Equipment Group considers the DIGITAL RADIOGRAPHY CXDI-401C Wireless device to be substantially equivalent to the predicate devices CXDI-401C COMPACT and CXDI-701C Wireless. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2014

Canon, Inc.
% Ms. Diane Rutherford
Submissions Manager
Ken Block Consulting
1201 Richardson Drive, Suite 280
RICHARDSON TX 75080

Re: K133693
Trade/Device Name: Digital Radiography CXDI-401C Wireless
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 23, 2014
Received: May 29, 2014

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.

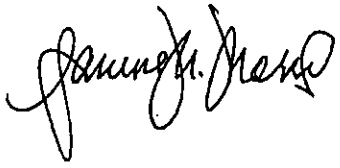
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
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)*
K133693

Device Name
Digital Radiography CXDI-401C Wireless

Indications for Use *(Describe)*
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.

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)*

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