5. 510(k) SUMMARY

Submitter: Canon, Inc. – Medical Equipment Group
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JUL 0 3 2013

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Date Prepared: April 15, 2013 *revised June 20, 2013*

Trade Name:
DIGITAL RADIOGRAPHY CXDI-701C Wireless
DIGITAL RADIOGRAPHY CXDI-701G Wireless
DIGITAL RADIOGRAPHY CXDI-801C Wireless
DIGITAL RADIOGRAPHY CXDI-801G Wireless

Common Name: Image Intensified Fluoroscopic X-Ray System

Classification Name: MQB 892.1650 Solid State X-Ray Imager (Flat Panel/Digital Imager)

Predicate Devices:
K102012 MQB CXDI-70C Wireless, Canon, Inc.
K112309 MQB DIGITAL RADIOGRAPHY CXDI-80C Wireless, Canon, Inc.
DIGITAL RADIOGRAPHY CXDI-80G Wireless, Canon, Inc.

Device Description: The four models of detectors included in this submission are solid state x-ray imagers. Models *CXDI-701C Wireless* and *CXDI-701G Wireless* have an approximate imaging area of 35.0 x 42.6 cm, while models *CXDI-801C Wireless* and *CXDI-801G Wireless* have an approximate imaging area of 35.0 x 27.4 cm

For all models, 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 all four of the proposed models, the dynamic range has been increased to allow for improved tonal precision. In addition, these models can detect x-ray irradiation without direct electrical connection to the x-ray generator, referred to as the Non-Generator Connection Mode. The x-ray flat panel detector integrates a real-time x-ray irradiation sensor as well as an imaging detector on the same detector surface. During the Non-Generator Connection Mode, the irradiation sensor is activated to detect the start of irradiation while the imaging detector is in the idling status. The detection of irradiation shifts the imaging detector to the image acquisition status instantaneously to obtain the x-ray image.

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5. 510(k) SUMMARY (continued)

Statement of Intended Use:

The DIGITAL RADIOGRAPHY CXDI-701G Wireless, CXDI-701C Wireless, CXDI-801G Wireless and CXDI-801C Wireless provide digital image capture for conventional film/screen radiographic examinations. These devices are intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. These devices are not intended for mammography applications.

Summary of Technological Characteristics:

Comparisons with the predicate devices show the technological characteristics of the proposed DIGITAL RADIOGRAPHY CXDI-701C Wireless, DIGITAL RADIOGRAPHY CXDI-701G Wireless, DIGITAL RADIOGRAPHY CXDI-801C Wireless, and DIGITAL RADIOGRAPHY CXDI-801G Wireless devices to be substantially equivalent to the predicate devices. The proposed devices are functionally identical to the predicate devices.

An additional change for the 701C/G and 801C/G models is that these models can detect x-ray irradiation without direct electrical connection to the x-ray generator, referred to as the Non-Generator Connection Mode. The x-ray flat panel detector integrates a real-time x-ray irradiation sensor as well as an imaging detector on the same detector surface. During the Non-Generator Connection Mode, the irradiation sensor is activated to detect the start of irradiation while the imaging detector is in the idling status. The detection of irradiation shifts the imaging detector to the image acquisition status instantaneously to obtain the x-ray image.

The dynamic range has been increased from the previously cleared values of approximately 4 digit with 14-bit Linear A/D and 12-bit Output Data, to the new values of approximately 4 digit with 16-bit Linear A/D and 16-bit Output Data. This modification allows for improved tonal precision and product performance.

Summary of Non-Clinical / Test Data:

Tests were performed on the four models 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 device(s). Documentation was provided demonstrating compliance of the CXDI-701G Wireless, CXDI-701C Wireless, CXDI-801G Wireless and CXDI-801C 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.

Testing confirmed that the CXDI-701G Wireless, CXDI-701C Wireless, CXDI-801G Wireless and CXDI-801C 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.

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5. 510(k) SUMMARY (continued)

Summary of Non-Clinical / Test Data: (continued)	Together, these verification/validation activities successfully demonstrated that the CXDI-701G Wireless, CXDI-701C Wireless, CXDI-801G Wireless and CXDI-801C 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-701G Wireless, CXDI-701C Wireless, CXDI-801G Wireless and CXDI-801C Wireless device.
Conclusion:	*Canon, Inc. – Medical Equipment Group* considers the DIGITAL RADIOGRAPHY CXDI-701C Wireless, DIGITAL RADIOGRAPHY CXDI-701G Wireless, DIGITAL RADIOGRAPHY CXDI-801C Wireless, and DIGITAL RADIOGRAPHY CXDI-801G Wireless devices 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.

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 3, 2013

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

Re: K131106
Trade/Device Name: Digital Radiography CXDI-701C/G, CXDI-801C/G Wireless
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: April 15, 2013
Received: April 19, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

INDICATIONS FOR USE

510(k) Number: **K131106**

Device Name: *DIGITAL RADIOGRAPHY CXDI-701C Wireless, DIGITAL RADIOGRAPHY CXDI-701G Wireless, DIGITAL RADIOGRAPHY CXDI-801C Wireless, DIGITAL RADIOGRAPHY CXDI-801G Wireless*

Indications for Use:

The DIGITAL RADIOGRAPHY CXDI-701G Wireless, CXDI-701C Wireless, CXDI-801G Wireless and CXDI-801C Wireless provide digital image capture for conventional film/screen radiographic examinations. These devices are intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. These devices are not intended for mammography applications.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131106