K103591

510(k) Summary

MAR 29 2011

Prepared: December 3, 2010

Submitter/Holder:

Company Name:	Canon Inc.
Company Address:	30-2 Shimomaruko 3-chome, Ohta-ku Tokyo 146-8501, Japan
Contact Person:	Naoyasu Asaka
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Proposed Device:

Reason For 510(k):	New Model
Trade Name:	Canon Inc.
Model Name:	DIGITAL RADIOGRAPHY CXDI-401G DIGITAL RADIOGRAPHY CXDI-401C DIGITAL RADIOGRAPHY CXDI-401G COMPACT DIGITAL RADIOGRAPHY CXDI-401C COMPACT
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Trade Name:	Canon Inc.
FDA 510(k) #/Model Name:	K102012/ DIGITAL RADIOGRAPHY CXDI-70C Wireless K090623/ DIGITAL RADIOGRAPHY CXDI-40G COMPACT K062221/ DIGITAL RADIOGRAPHY CXDI-40EC K050987/ DIGITAL RADIOGRAPHY CXDI-40EG
Classification Name:	90MQB, Solid State X-ray Imager

Description of Device:

The DIGITAL RADIOGRAPHY CXDI-401G, CXDI-401C, CXDI-401G COMPACT and CXDI-401C COMPACT are solid state x-ray imagers which have 41.5 x 42.6cm imaging area. The device intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo-detectors that create an electrical signals. After the electrical signals are generated, it is converted to digital value, and the images will be displayed on monitors.

The CXDI-401G and CXDI-401G COMPACT use GOS (Gadolium Oxy-Sulfide) as the material for fluorescent screen, while CXDI-401C and CXDI-401C COMPACT use CsI (Cesium Iodide) which provides high x-ray absorption as fluorescent screen.
The CXDI-401G COMPACT and CXDI-401C COMPACT employ housing for easy installation in stand unit and table unit.

Intended Use:

DIGITAL RADIOGRAPHY CXDI-401G, CXDI-401C, CXDI-401G COMPACT and CXDI-401C COMPACT 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.

Section 5: 510(k) Summary

Comparison to Predicate:

The imaging principle and intended use of the DIGITAL RADIOGRAPHY CXDI-401G, CXDI-401C, CXDI-401G COMPACT and CXDI-401C COMPACT are the same as those of the predicate devices (CXDI-70C Wireless, CXDI-40G COMPACT, CXDI-40EC or CXDI-40EG).

Performance testing:

The Electrical safety, Electromagnetic compatibility and other performance testings were performed on these devices which demonstrated that these devices are safe and effective, and are equivalent to the predicate devices.

Conclusion:

The Performance Data demonstrate that CXDI-401G, CXDI-401C, CXDI-401G COMPACT and CXDI-401C COMPACT are as safe and effective as the predicate devices (DIGITAL RADIOGRAPHY CXDI-70C Wireless, CXDI-40G COMPACT, CXDI-40EC or CXDI-40EG). Based on the information in this submission, similarity to the predicate devices, and the results of our design control activities and non-clinical testing, it is the opinion of Canon Inc. that the DIGITAL RADIOGRAPHY CXDI-401G, CXDI-401C, CXDI-401G COMPACT and CXDI-401C COMPACT described in this submission are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc. – Medical Equipment Group
% Mr. Koji Kubo
Manager
Cosmos Corporation – Tokyo Office
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TACHIKAWA-SHI TOKYO 190-0012
JAPAN

AUG 23 2013

Re: K103591
Trade/Device Name: CXDI-401G, CDXI-401C, CDXI-401G COMPACT and CDXI-401C
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 25, 2011
Received: February 28, 2011

Dear Mr. Kubo:

This letter corrects our substantially equivalent letter of March 29, 2011.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K103591

Device Name: CXDI-401G, CXDI-401C, CXDI-401G COMPACT, CXDI-401C COMPACT

Indications for Use:

DIGITAL RADIOGRAPHY CXDI-401G, CXDI-401C, CXDI-401G COMPACT and CXDI-401C COMPACT 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.
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Prescription Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103591