K060433

510(k) Summary

Prepared: December 9, 2005

Submitter:

Company Name: Canon USA, Inc. (U.S. agent for Canon Inc.)
Company Address: One Canon Plaza
Lake Success, NY 11042
Contact Person: Ms. Sheila Driscoll
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Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-50C
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-50G
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K031447

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40C
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K031633

Description Of Device: The Canon digital radiography CXDI-50C is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon digital radiography CXDI-50C is different from CXDI-50G and CXDI-40C in the following respect:

- The CXDI-50C is a portable unit as same as the CXDI-50G. It is positioned on a table or installed in a holder for a stand or a table during its operation as is the case with a film cassette, while the CXDI-40C operates in conjunction with an upright stand, table, and universal stand.
- Both the CXDI-50C and the CXDI-50G use the same amorphous silicon alley as the sensing means, however, the

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CXDI-50C uses the different material for fluorescent screen which is deposited on the amorphous silicon array with from the CXDI-50G. The CXDI-50C uses CsI (Cesium Iodide) while CXDI-50G uses GOS (Gadolium Oxy-Sulfide). Because of CsI which provides high x-ray absorption as fluorescent screen, CXDI-50C delivers diagnostic images with the x-ray dosage less than that required by CXDI-50G and CXDI-50C's DQE approximately doubles compared to CXDI-50G.

The principle of the CXDI-50C is the same as the CXDI-40C, with some modifications of its housing in size and shape. The sensor of the CXDI-50C has the same characteristics as the CXDI-40C and the imaging area is changed from 43x43cm to 35x43cm.

The CXDI-50C itself is a component without a control PC. Using a general-purpose computer with appropriate specifications and the designated system software installed in it, as a control PC, the CXDI-50C achieves performance stated herein(such as image capturing, DICOM transfer and etc.)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Canon, Inc.
% Mr. Morten S. Christensen
Program Reviewer
Underwriters Laboratories, Inc.
12 Laboratory Drive, P.O. Box 13995
Research Triangle Park, NC 27709-3995

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Re: K060433
Trade/Device Name: CXDI-50C
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 8, 2006
Received: February 21, 2006

Dear Mr. Christensen:

This letter corrects our substantially equivalent letter of March 10, 2006.

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): K060433

Device Name: CXDI-50C

Indications For Use:

DIGITAL RADIOGRAPHY CXDI-50C provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060433