K031447

510(k) Summary

MAY 21 2003

Prepared: March 26, 2003

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
Phone Number: (516) 328-5602
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Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-50G V6.0
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-31/CXDI-40G
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K003689/K023750

Description Of Device:

The Canon digital radiography CXDI-50G 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-50G is different from CXDI-31 and CXDI-40G in the following respect:

- The CXDI-50G is a portable unit as same as the CXDI-31. It is positioned on a table or installed in a holder during its operation as a film cassette is while the CXDI-40G operates in conjunction with an upright stand, table, and universal stand.

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

The CXDI-50G 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-50G achieves performance stated herein (such as image capturing, DICOM

transfer and etc.) K031447

Intended Use:

Canon digital radiography CXDI-50G 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.

Descriptive Comparison

The predicate devices are the Canon digital radiography CXDI-40G cleared under Document Number K023750 on November 22, 2002 and CXDI-31 cleared under Document Number K003689 on January 2, 2002.

The CXDI-50G's technical specifications, imaging principle, physical characteristics and intended use are the same as those of the CXDI-40G including pixel pitch. However, the differences in the design are as follows:

- The mechanical structure and physical appearance of the CXDI-50G are different than the CXDI-31 and the CXDI-40G. Additional information can also be found in the CXDI-50G User's Manual provided in this submission.

- A removable, fixed grid is used for the CXDI-50G the same as the CXDI-31 and the CXDI-40G. The both grids for the CXDI-50G and the CXDI-31 are installed outside the sensor housing, while the gird for the CXDI-40G is instated inside the sensor housing. Both types of grids are used for eliminating the scatter X-ray in exposures that use films.

Regarding the software:

- The system software for controlling CXDI-50G is released as V6.0.
- V6.0 includes some changes from V5.0.
- The main changes of the V6.0 are the addition of the control of CXDI-50G sensor and some change of GUI.
- V5.0 was first introduced and cleared under K023750 and is currently used in Canon models the CXDI-40G.

Based on the information in this submission, similarity to the predicate devices (the Canon digital radiography CXDI-31 and the CXDI-40G), and the results of our design control activities, it is our opinion that the Canon digital radiography CXDI-50G described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Canon, Inc.
% Mr. Joseph Murnane
Senior Staff Engineer
Underwriters Laboratories, Inc.
Melville Division
1285 Walt Whitman Road
MELVILLE NY 11747-3081

Re: K031447
Trade/Device Name: Canon, Digital Radiography Model CXDI-50G
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: May 7, 2003
Received: May 7, 2003

Dear Mr. Murnane:

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 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 3: Statement

Indications Statement

510(K)Number(if known): K031447

Device Name: CANON DIGITAL RADIOGRAPHY CXDI-50G-V6.

Indications for Use:

CANON DIGITAL RADIOGRAPHY CXDI-50G 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.

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031447