JUN 11 2003

Section 10: Summary

K031633

510(k) Summary

Prepared: April 8, 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
Fax Number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40C V6.0
Classification Name:	MQB, Solid State X-ray Imager
Regulation Number:	892.1630
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40G V6.0
Classification Name:	MQB, Solid State X-ray Imager
Regulation Number:	892.1630
FDA 510(k) #:	K023750

Description Of Device:

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

- Both the CXDI-40C and the CXDI-40G use the same amorphous silicon alley as the sensing means, however, the CXDI-40C uses the different material for fluorescent screen which is deposited on the amorphous silicon array with from the CXDI-40G. The CXDI-40C uses CsI (Cesium Iodide) while CXDI-40G uses GOS (Gadolium Oxy-Sulfide). Because of CsI which provides high x-ray absorption as fluorescent screen, CXDI-40C delivers diagnostic images with approximately half the x-ray dosage required by CXDI-40G and CXDI-40C's DQE approximately doubles compared to CXDI-40G.

Since the same amorphous silicon array is used, the CXDI-40C's imaging size, number of pixels and pixel pitch are the same as those of CXDI-40G. CXDI-40C as well as CXDI-40G operates in conjunction with an upright stand, table, and universal stand. CXDI-40C's housing size and shape are almost as same as those of CXDI-40G.

K031633

Control PC is required to operate the CXDI-40C as well as the predicate devices.

Intended Use:

Canon digital radiography CXDI-40C 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.

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

JUN 11 2003

Canon, Inc.
% Ms. Susan Gill
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K031633
Trade/Device Name: Digital Radiography Model CXDI-40C
Regulation Number: 21 CFR 892.1630
Regulation Name: Solid state x-ray imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: May 23, 2003
Received: May 27, 2003

Dear Ms. Gill:

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): K031633

Device Name: Digital Radiography CXDI-40C V6.0

Indications for Use:

CANON DIGITAL RADIOGRAPHY CXDI-40C 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)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031633