

OCT 13 1999

K 99 2547

Canon

510(k) Summary

CANON U.S.A., INC.
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LAKE SUCCESS, NY 11042-1198
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Prepared: July 19, 1999

Submitter:

Company Name: Canon USA, Inc. (U.S. designated agent for Canon Inc.)
Company Address: One Canon Plaza
Lake Success, NY 11042
Contact Person: Ken Shadoff, Senior Product Safety Engineer
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-22
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-11
Classification Name: 90MQB, Solid State X-ray Imager
FDA 510(k) #: K981556

Description Of Device:

The Canon X-ray digital camera model CXDI-22 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.

Canon X-ray digital camera CXDI-22 is different from CXDI-11 in the following respect:

- Model CXDI-11 operates in conjunction with an upright stand, while model CXDI-22 is a retrofit kit for installation into an existing radiologic table.

Intended Use:

Canon X-ray digital camera CXDI-22 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.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.

Table of comparison

Item		CXDI-11	CXDI-22
Intended Use		Provide diagnostic images for general radiography with upright system	Provide diagnostic images for general radiography with table system
Desgin		Digital acquisistion, electronic processing	Same
Energy Uses		Receives x-radiation generated by external x-ray generator	Same
Materials	X-ray Absorber	Fluorescent screen($Gd_2O_2S:TB^{3+}$) Visible emission peak: 545nm	Same
	Sensing Means	Amorphous Silicon W/TFT Array Detection peak:540-620nm	Same
Anatomical Sites		General radiography	Same
Target Population		General population	Same
Physical Safety		Minimize exposure to x-radiation	Same
Compliance with Standard		Complies with IEC 601-1-2	Same
Biocompatibility		N/A	N/A
Performance		After digital processing(optimize the gray-scale)	Same
Labeling		Approved 510(K)	See attachment labeling
MTF		MTF@2lp/mm 42%	Same
Dynamic Range		Dyanamic range: approximately 4 digit (linear A/D : 14bit) (output data : 12bit)	Same
Sensor Unit		552 x 598 x 231mm	604 x 645 x 73.5or69mm
Power Supply		580 x 489 x 275mm	390 x 160 x 110mm
Control PC		483.5 x 594 x 300mm	453 x 594 x 300mm
Operation Unit		298 x 209.5 x 130mm	Same
Card Reader		50 x 180 x 39mm	Same
Stand		900 x 475 x 2100mm	N/A
Table		N/A	N/A



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

Mr. Ken Shadoff
Senior Product Safety Engineer
Canon USA, Inc.
One Canon Plaza
LAKE SUCCESS NY 11042-1198

AUG 23 2013

Re: K992547
Trade/Device Name: Model CXDI-22 X-ray Digital Camera
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 29, 1999
Received: July 30, 1999

Dear Mr. Shadoff:

This letter corrects our substantially equivalent letter of October 13, 1999.

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.

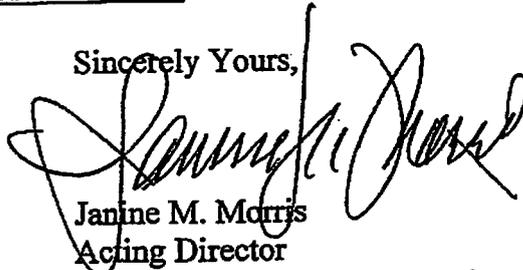
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Statement

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510(K)Number(if known): K992547

Device Name: CXDI-22

Indications for Use:

CANON X-RAY DIGITAL CAMERA CXDI-22 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 ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation(ODE) _____

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992547