

NOV 4 1998

510(k)Summary

1. Date Prepared: April 1, 1998
2. Applicant's Name: Canon USA, Inc.  
One Canon Plaza.  
Lake Success, NY 11042  
  
Mr. Glenn Impal/Mr. Ken Shadoff  
Phone: (516)328-5600  
Fax: (516)328-5169
3. Model Name: CANON X-RAY DIGITAL CAMERA CXDI-11  
90MQB, Solid State X-ray Imaging Device
4. Predicate Model: Radiographic Film (892.1840)  
Radiographic Intensifying Screen (892.1960)
5. Device Description: CANON X-RAY DIGITAL CAMERA CXDI-11 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 digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.  
CANON X-RAY DIGITAL CAMERA CXDI-11 differs from traditional X-ray systems in that instead of exposing a film for subsequent wet chemical processing to create a hardcopy image, a device is used to capture the image in electronic form. The digital data are then used to produce diagnostic hardcopy and reference-softcopy images.
6. Intended Use: CANON X-RAY DIGITAL CAMERA CXDI-11 is indicated for use in generating radiographic Images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.
7. Comparison to predicate Device  
CANON X-RAY DIGITAL CAMERA CXDI-11 device uses an electronic readout of an image while conventional film/screen systems require chemical processing to produce image.  
CANON X-RAY DIGITAL CAMERA CXDI-11 device produces a digital image while conventional film/screen systems produce an analog image.

# 510(K) Summary (continued)

## Clinical Evaluation of Canon Digital Radiography System, Model CXDI-11

A study was conducted to evaluate whether image quality of film obtained from the Canon Digital Radiography System is substantially equivalent to conventional x-ray film. Qualified readers evaluated both digital and analog films from various inpatient cases. Films were evaluated for overall image quality, as well as for image quality with respect to specific anatomical areas. The difference between image quality scores for digital and analog film consistently indicated that the quality of the two types of film was equivalent or that digital film was of higher quality. Several different statistical techniques were used to confirm this finding.

To evaluate the consistency of the study readers, a number of analog films were read twice by each reader, separated by a period of time. Results showed that readers were able to read the films in a consistent fashion, but that the magnitude of difference between their two readings was comparable to the difference between the two types of film.

It can be reasonably concluded that the image quality of films obtained with Canon's Digital Radiography System is substantially equivalent to that obtained with conventional analog film.

Table of comparison

Item		CXDI-11	Screen-Film system	Comment
Intended Use		Provide diagnostic images for general radiography use	Same	N/A
Design		Digital acquisition, electronic processing	Analog acquisition, chemical processing	N/A
Energy Uses		Receives x-radiation generated by external x-ray generator	Same	CXDI-11 operates from AC power source
Materials	X-ray Absorber	Fluorescent screen (Gd <sub>2</sub> O <sub>2</sub> S:Tb <sup>3+</sup> ) Visible emission peak : 545nm	Same	In Screen-Film system, a film sandwiched in between fluorescent screen although a fluorescent screen is placed in front of the sensor panel in CXDI-11.
	Sensing Means	Amorphous Silicon W/ TFT Array Detection peak: 540nm ~ 620nm	Silver halide film Detection peak: 430nm ~ 680nm	Screen-Film system image is blurred more with diffusion of two fluorescent screen which are placed both sides of film.
Anatomical Sites		General radiography	Same	N/A
Target Population		General population	Same	N/A

Physical Safety	Minimize exposure to x-radiation	Same	N/A
Compliance with standards	Complies with IEC 601-1-2	N/A	N/A
Biocompatibility	N/A	N/A	N/A
Performance	After digital processing (optimize the gray-scale)	Development of film (use the own gray-scale)	CXDI-11 performs the digital image processing, and can optimize its image visualization even after exposure. Films in Screen-Film system has their own H-L character, and its gray-scale is fixed by exposure condition.
Labeling	See attached labeling	N/A	N/A
MTF	MTF@2lp/mm 42%	MTF@2lp/mm 33% (Lanex 250/TMS-RA) (Kodak)	The CXDI-11 sensor plate itself does not have blur theoretically.
Dynamic Range	Dynamic range: approximately 4 digit (linear A/D : 14 bit) (output data : 12 bit)	Dynamic range: approximately 1.5 digit	CXDI-11 can utilize wider dynamic range to control the image visualization.



NOV 4 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ken Shadoff  
Senior Product Safety Engineer  
Quality Management Dept.  
Cannon U.S.A., Inc.  
One Cannon Plaza  
Lake Success, NY 11042-1198

Re: K981556  
Canon X-Ray Digital Camera CXDI-11  
Dated: August 19, 1998  
Received: September 14, 1998  
Regulatory class: Unclassified  
Procode: 90 MQB

Dear Mr. Shadoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications Statement

Page \_\_\_\_\_ of \_\_\_\_\_

510(K)Number(if known): K981556

Device Name: Canon CXDI-11

Indications for Use:

CANON X-RAY DIGITAL CAMERA CXDI-11 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 Form 1-2-96)

*David A. Sporn*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K981556