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K992955
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2.1 Summary for Public Disclosure

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Date summary was prepared

August 24, 1999

Name(s) of the device

Trade name Xplorer 1000 Digital X-ray Imager
Common name Digital X-ray Imager

Classification name Solid State X-ray Imager

Identification of predicate device(s)

Equivalency is based on the IMIX DIGITAL THORAX SYSTEM (K974863) and conventional radiographic film (21 CFR 892.1840).

Description of the device

The Xplorer 1000 is an optical based digital x-ray imager. It works by converting incident x-ray energy to visible light by use of fluorescent screen. The visible light is deflected by a mirror to a high resolution CCD camera that produces a digital image. The device trigger mechanism ensures that image is captured when the x-ray beam is turned on. The device does not require any connection to the x-ray generator.

Intended Use

The Xplorer 1000 is a digital x-ray imager intended as a replacement for x-ray film for general human radiography.

Comparison of device characteristics to predicate

Feature	Xplorer 1000	IMIX	Film / Screen
510(k)/Regulation	Pending	K974863	892.1840
Intended Use	General Human Radiography		
Fluorescent screen to convert x-rays to light	Yes	Yes	Yes
Mirror to separate x-rays from light	Yes	Yes	No
Lens to focus light	Yes	Yes	No
CCD to capture image	Yes	Yes	No
Spatial Resolution (microns) at 100% MTF	127	200	<100

Non-clinical testing

The Xplorer 1000 uses a fluorescent screen of the type used in film / screen radiography to convert x-rays to light. This light is then captured by a high resolution CCD sensor.

To verify the spatial resolution and determine its equivalence to film, tests were performed using line pair resolution targets and radiological phantoms. Resolution was found to exceed the standards set by the American College of Radiologists and, qualitatively, imaging of bone detail, particularly trabeculae, was found equivalent by radiologists.

Clinical testing

In an image quality study, 20 human subjects were x-rayed both conventionally and with the Xplorer 1000. A range of anatomy was covered representative of general radiography. The results were examined by a panel of 3 radiologists and found equivalent to film.

Conclusion

Imaging Dynamics concludes that the Xplorer 1000 Digital X-ray Imager is equivalent to the Imix Digital Thorax System (K974863) and conventional radiographic film (21 CFR 892.1840) based upon the following criteria:

- the Xplorer 1000 has the same intended use as the predicate devices; and,
- the Xplorer 1000 has radiographic performance equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Robin Winsor
Director-Regulatory Affairs
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Canada T2E 8M5

Re: K992955
Xplorer 1000
Dated: April 21, 2000
Received: April 24, 2000
Regulatory class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Mr. Winsor:

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 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). 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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

2.3 Indications for Use Statement

Ver/ 3 – 4/24/96
Applicant: Imaging Dynamics Corporation
510 (k) Number (if known): K992955
Device Name: Xplorer 1000 Digital X-ray Imager
Indications For Use:

Intended for use in general human radiography imaging similar to the optically coupled CCD based device cleared under 510(k) number K974863.

Not to be used for mammography.

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

Concurrance of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, **ENT,** and Radiological Devices
510(k) Number K992955