K032654

OCT - 9 2003

510(k) Summary
for
PcCR Digital Imaging Devices for X-Ray Systems

1. DATE SUMMARY PREPARED

August 26, 2003

2. SUBMITTER'S NAME AND ADDRESS

Orex Computed Radiography Ltd.
Yoqneam "Star" Bldg.
Yoqneam, P.O. Box 465
NESHER 36603
ISRAEL

3. CONTACT PERSON

Moshe Shenhav
Telephone: 011 972 4 959 1331
Facsimile: 011 972 4 959 1262

4. DEVICE NAME

Trade/Proprietary Name: PoRT Cassette
Common Name: Accessory to Electrostatic X-ray imaging system
Classification Name: Accessory to Electrostatic X-ray imaging system

5. PREDICATE DEVICES

The legally marketed device to which equivalence is being claimed is: Kodak EC-L Cassette/EC-V Verification System for Portal Imaging (K960834)

6. DEVICE DESCRIPTION

The PoRT Cassette is an optional cassette to be used with the PcCR Digital Imaging Devices for portal imaging. The PcCR Digital Imaging Devices are filmless systems intended for digital radiography using a phosphor storage screen which were cleared under K003256. The PcCR Digital Imaging device enables the clinician to scan or import images for display, review, or storage in a database. The PcCR device consists of reusable phosphor storage screens for recording radiographic images, an

image reader/digitizer, and software for displaying, enhancing, and storing radiographs using a user-provided personal computer. The PoRT Cassette is optional cassette to be used with the PcCR System and is also a reusable phosphor screen. It is offered in 14" x 17" size. Other than the addition of the PoRT Cassette and a software upgrade, the PcCR Digital Imaging Device is identical to that described in K003256.

7. INTENDED USE

The PoRT Cassette is an accessory to the PcCR Digital Imaging Device and is indicated for portal imaging (Radiation Therapy Quality Control).

8. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Orex Computed Radiography Ltd. bases the claim of equivalence to cited predicate devices upon similarities in intended use, technological characteristics, and operational characteristics. Bench testing and clinical validation demonstrate that the PoRT Cassette performs according to specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Orex Computed Radiography, Ltd.
% Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K032654
Trade/Device Name: PoRT Cassette
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 IXK
Dated: August 26, 2003
Received: August 28, 2003

Dear Ms. McNamara-Cullinane:

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

510(k) Number (if known): K032654

Device Name: PoRT Cassette

Indications for Use:

The PoRT Cassette is an accessory to the PcCR Digital Imaging Device and is indicated for portal imaging (Radiation Therapy Quality Control).

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032654

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

(Optional Format 1-2-96)