K073670

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: Point of care including LLI

Establishment Name and Registration Number of Submitter

Name: OREX Computed Radiography Ltd
Registration: 3003343596
Owner: CARESTREAM HEALTH, INC
Submission contact: Dan Laor

JAN 25 2008

Device Classification

Device Code:	MQB
CFR Section:	892.1650
Name:	CR- Computerized radiography
Classification:	Class II Product
Review Advisory Committee:	Radiology

Reason for 510(k) Submission

Special 510(k) Submission

Identification of Legally Marketed predicate Devices

i. Orex unmodified predicate device: (K003256) PcCR DIGITAL IMAGING, including the (K032654) PORT CASSETTE

ii Kodak unmodified predicate device: (K021829) Kodak DirectView CR Long Length

Device Description

Point of care including LLI is a Computer Radiography (CR) acquisition scanner, which includes mechanical and software interface to the LLI cassette. The device is constructed from a Man Machine Interface panel, a CR scanner and infrastructure, which enables connection to external applications, i.e. to import command messages, to export images and provide status messages. The LLI is a CR cassette, which is used for Long Length Imaging X Ray examinations of long areas of anatomy.

Indications for use

The Point-of-Care is intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images.
The LLI is indicated for Long Length Imaging examinations of long areas of anatomy such as the leg and spine.

Safety & Effectiveness

The device has been designed, verified and validated in compliance with the 21CFR 820.30 regulations. Bench and clinical data demonstrate that the device meets the required specifications. No adverse affects have been detected.

Substantial Equivalency

Orex opines that the Point of Care including the LLI is substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Moshe Shenhav
Director, QA & Regulatory Affairs
OREX Computed Radiography Ltd.
Star Bldg. Yokneam, P.O. Box 505
Yokneam 20692
ISRAEL

Re: K073670
Trade/Device Name: Point of Care including LLI
Regulation Number: 21 CFR §892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 6, 2007
Received: December 27, 2007

Dear Mr. Shenhav:

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 such 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K073670

Device Name: Point of Care including LLI

Indications for Use: The Point-of-Care is intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images.
The LLI is indicated for Long Length Imaging examinations of long areas of anatomy such as the leg and spine.

Prescription Use: **YES** AND/OR Over-the-Counter Use: NO
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073670