K973219

Summary of Safety and Effectiveness

Device proprietary name:	AMBER DU
Classification name:	Stationary X-ray System (90-KPR)
Establishment Registration Number:	1180516 Oldelft Corporation of America 9108 Guilford Road Columbia, MD 21046
Owner/Operator and Manufacturer:	Oldelft BV Roentgenweg 1, 2624 BD Delft P. O. Box 5082, 2600 GB Delft The Netherlands
Establishment Registration No:	9611894
Owner/Operator Number:	8030474
Classification:	Class II
Product code:	90-KPR (Stationary X-ray System)
CFR Citation:	21 CFR 892.1680 Tier I submission
Panel:	Radiology
Performance standard:	21 CFR 1020.30 and 21 CFR 1020.31
Accession number:	8811863

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The Oldelft Amber DU is comprised of the currently marketed Oldelft Amber AU, the Lumisys Lumiscan 75 LASER Film Digitizer which is commercially available, and a digital workstation based on a commercially available workstation from Rogan Imaging Corporation using software written by Rogan to Oldelft's specifications. The workstation displays screens to the operator for data input and for data and image display. The Oldelft Amber DU display is configured as a shell about the Rogan software which operates in the background to perform essential functions and to provide miniPACS features to Amber DU and allow the importation of patient demographic information and to allow the exportation of digital image data into which patient demographics have been incorporated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 8 1997

L Don Phillips
Oldelft Corporation of America
9108 Guilford Rd.
Columbia, MD 21046

Re: K973219
Amber DU (Chest Unit)
Dated: August 25, 1997
Received: August 27, 1997
Regulatory class: II
21 CFR 892.1680/Procode: 90 KPR

Dear Mr. Phillips:

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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin

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

Statement of indications for use

510(k) Number (if known): K973219

Device Name: Amber DU

Indications for Use:

Amber DU provides the Radiologist the ability to acquire chest images on film, to digitize these images real time for analysis on the Operator Workstation and retain the ability to analyze the films on a conventional lightbox, and to export the digital images Dicom 3 conformant to the hospital's network server for storage and eventual retrieval if desired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973219