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Oldelft B.V.
Röntgenweg 1, 2624 BD Delft
P.O. Box 5082, 2600 GB Delft
The Netherlands
Tel.: +31 (0) 15 269 89 00
Fax: +31 (0) 15 269 84 88
Trade Register No.: 260.30.374
Vat No.: NL 008897852 B 06
Bankers: ABN AMRO
Account no.: 47.95.05.683

K980296

21 january 1998

Summary of Safety and Effectiveness

Device proprietary (trade) name:	Digidelca (Digidelca-M, Digidelca-C, Digidelca-DES)
Classification name:	Stationary X-ray System (90-KPR)
Establishment Registration Number:	1180516 Oldelft Corporation of America 9108 Guilford Road Columbia, MD-21046
Owner/operator:	Oldelft BV Röntgenweg 1 Postbus 5082 NL-2600 GB Delft The Netherlands
Establishement Registration Number:	9611894
Owner/operator Number:	8030474
Classification:	Class II
Product Code:	90-KPR (Stationary X-Ray System)
CFR Citation:	21 CFR 892.1680 Tier 1 submission
Panel:	Radiology
Intended use:	Clinical or mass chest radiography
Performance standard:	21 CFR 1020.30 and 21 CFR 1020.31

European: Medical Device Directive (93/42/EEC)
EMC Directive (89/336/EEC)

Description:

Digidelca is a product which was developed around hardware and software components which are already market within the United States and therefore substantial equivalence is claimed to Electrodelca for the electrical, mechanical and optical system layout and to AMBER-DU and HyperPACS for the software configuration:

- The Oldelft Electrodelca (tm) mass chest x-ray system (K892659) for the camera housing basic design, the image intensifier tube, the elevator stand basic design and the compatible x-ray tube and high voltage generator selection. The image capturing device in Digidelca is a TDI CCD sensor, instead of radiographic film.

- The Rogan HyperPACS (tm) software package (K950343) for the principal software tasks for the Operators Workstation: image acquisition and storage, image export, network interfacing.

- The Oldelft Amber-DU (K973219) software package (reconfigured) for user interfacing at the Operators Workstation.

The Operators Workstation displays screens to the operator for data input and for data and image display. The Digidelca software is configured as a dedicated shell around the Rogan software which operates in the background to perform essential functions for data acquisition, image storage and image export. The OWS allows for importing patient demographic information and exportation of digital images into which patient demographics have been incorporated (DICOM compatible data structures).

The Date Entry System is an additional pc platform which is used to copy patient demographics to a card format information carrier by a thermal printing process. The card is handed out to the examinee who will submit it to the Digidelca(-M) operator prior to making his/het x-rays. Patient demographics are scanned from the card by a two dimensional barcode reader and thereby entered into the Digidelca(-M) operators workstation.

Non-clincial tests: In-house prototype tests include a.o. resolution and contrast measurements which are reported in Tab N of this application and which show comparable results as for Electrodelca.

Clinical tests: Digidelca is successfully operational at a beta test site in The Netherlands (Twenteborg Hospital, Almelo) since mid 1997 and is clinicaly used for both in-patients and out-patients. It replaced the Electrodelca available there before, and images are generally appreciated by radiologists as "better" then those from Electrodelca.

Conclusion: Digidelca is a reliable system for chest

screening with enhanced imaging performance when compard to Electrodelca. Digital augmentations have proved to be very useful.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 1998

Ernest King
Service Manager
Oldelft Corporation of America
9108 Guilford Road
Columbia, MD 21046

Re: K980296
Digidelca, Stationary X-Ray System
Dated: Janauary 21, 1998
Received: January 27, 1998
Regulatory class: II
21 CFR 892.1680/Procode: 90 KPR

Dear Mr. King:

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

Statement of Indications for Use

510(k) Number (if known): K980296

Device Name: Digidelca

Indications for Use:

Digidelca provides the radiologists or pneumologists the ability to acquire chest x-ray images by filmless radiography (digital radiography), based on CCD technology. The x-ray transmission profile of the chest is converted into an electronic, digital image in real-time. Chest images become available for preview by the x-ray technician on the operators workstation only seconds after the x-ray exposure. After acceptance by the tech, digital (DICOM) images can be stored on electronic media, as e.g. CD-ROM, magnetic disk, or be exported to a (DICOM/PACS) network, c.q. clinical review station or to a film printer.

Note: PACS, networks, clinical review stations and (laser-) film printers are not considered part of the Digidelca system for which this application is filed, only external interfacs to this type of equipment are defined.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980296

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)