

FOI 510(k) Summary

K972191

In conformance with Section 513(l)(3) of the Food, Drug, and Cosmetic Act, Howtek Incorporated hereby submits with this Premarket Notification an adequate summary of any information.

1.1 Submission Date: May 19, 1997

1.2 Owner / Operator: Howtek Incorporated
21 Park Avenue
Hudson, New Hampshire 03051

SEP - 8 1997

1.3 Official Correspondent: M. Russell Leonard
Chief Operating Officer

1.3 Device Common / Usual Name: Teleradiology System

1.4 Device Trade Name: DIGITIZER DIRECTOR

1.5 Classification Name: PACS
Class II
Teleradiology Device
PAC Peripheral Device

1.6 Predicate or Legally Marketed Devices: Star Technologies
FISS (Film Image Scan System)
#K952914

Manufactured by Star Technologies, Inc.
515 Shaw Rd
Sterling, VA 20166

1.7 Description of Device:

DIGITIZER DIRECTOR is a DICOM 3.0 compliant secondary image capture application for the Howtek family of film digitizers. It is a query / retrieve service class provider (QRSCP). DIGITIZER DIRECTOR queries the designated DICOM 3.0 database as each patient record is created. Association is made with the patients already existing in the database. New patient information is required when no association is made. When patient information is complete, the entire patient record is sent to a designated DICOM entity, such as a database or viewing station. DIGITIZER DIRECTOR is a Microsoft Windows NT or Windows 95 based application.

1.8 Intended Use:

DIGITIZER DIRECTOR is a DICOM software package which enables any medical facility PC with adequate memory and film digitizer to perform a secondary image capture of films using the Howtek film digitizer family. DIGITIZER DIRECTOR is an integrated DICOM network product which does not have any compression capability. The operator uses the film digitizer to capture films. DIGITIZER DIRECTOR translates the images from digitizer format to DICOM format and sends them on to another DICOM application.

1.9 Software Development

Howtek certifies that the DIGITIZER DIRECTOR software is designed, developed, tested and verified according to ISO 9001 procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software used in this product is used for teleradiology and / or image storage only and does not effect image quality.

2.0 Statement of Substantial Equivalence

Substantial Equivalence Chart (DIGITIZER DIRECTOR)

Function of Variable	Howtek DIGITIZER DIRECTOR	Star Technologies FISS
Input	Digital Image from film digitizer in proprietary format	Digital Image from film digitizer in proprietary format
Function Performed	Conversion to DICOM 3.0 Format	Conversion to DICOM 3.0 Format
Output	Sent image to specified DICOM application	Sent image to specified DICOM application
Store and Forward Option	Yes	Yes
Image buffering during Network Downtime	Yes	Yes
Compression	No	No

Summary Statement of Safety and Effectiveness

In accordance with the provisions of the Safe Medical Device Act of 1990, Howtek, Inc. provides this summary of safety and effectiveness information regarding DIGITIZER DIRECTOR.

1.1 General Safety and Effectiveness

The device labeling contains instructions for use and indications for use.

The hardware components specified (but not supplied) are all off-the-shelf computer components.

1.2 Validation of Effectiveness

Extensive testing of the software package has been performed by programmers, by non-programmers and by potential customers. Software is only used for control purposes and has no bearing on image quality. There is no image processing or compression used with this software.

1.3 Substantial Equivalence

Howtek's DIGITIZER DIRECTOR is used for secondary image capture of digitized films and for transmission of these images to DICOM applications. The intended use and technological characteristics of the system are similar to the Star Technologies FISS. Any differences between the device and the predicate device have no significant influence on the safety or effectiveness of the product.

It is our conclusion that there is no software component that we know of in the Howtek DIGITIZER DIRECTOR Application whose failure or latent system design flaw would be expected to result in death or injury to a patient.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

M. Russell Leonard
Chief Operating Officer
Howtek, Inc.
21 Park Avenue
Hudson, NH 03051

Re: K972191
Digitizer Director (Secondary Image
Capture Software)
Dated: June 4, 1997
Received: June 10, 1997
Unclassified
Prococode: 90 LMD

SEP - 8 1997

Dear Mr. Leonard:

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, 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

Attachment C
Indications For Use Statement

510(k) Number (if Known): K972191

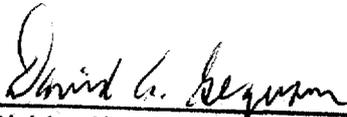
Device Name: Howtek DIGITIZER DIRECTOR

Indications for Use:

DIGITIZER DIRECTOR is a DICOM compatible software package which enables any medical facility personal computer (PC) with adequate memory and the appropriate film digitizer to perform secondary image capture of films using the Howtek film digitizer family. DIGITIZER DIRECTOR does not have any image compression capability. DIGITIZER DIRECTOR is an integrated DICOM network product which translates the images from proprietary digitizer format to DICOM format and sends them on to another DICOM application.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


David G. Bejerman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972191

Prescription Use: X

OR

Over-The-Counter Use: _____