FOI 510(k) Summary

K970908

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

Submission Date: March 5, 1997

MAY 20 1997

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

Device Common / Usual Name: Film Digitizer

Device Trade Name: Howtek 960

Classification Name: Digitizer, Film (90LMA)
Class II
Teleradiology Device
PAC Peripheral Device

Predicate or Legally Marketed Devices: Howtek Scanmaster DX
Film Digitizer

Description of Device:

The device is a transparency, charge coupled device (CCD) scanner which can be used to digitize radiographs or X-ray film. The digitizer reads gray digital information from the image and sends the raw data file to a host computer, for use with a Picture Archiving and Communication (PAC) System or teleradiology software package currently in the market place as separately approved third party software packages or complete PAC system. The user interface for the film digitizer resides in the host application software program.

The 960 creates a digital image file from transparent originals. The digital image file is expressed in either 8 or 12 bit gray level file format. The digitizer is connected to a host computer (either PC, Mac or UNIX) via SCSI II. There is no "activate" button the 960. To start an image capture operation, the user must activate the digitizer user interface on the host computer.

Overall, The 960 uses a film fed drive which transports the film over the camera as it digitizes the image. Each scan line is captured by the charge coupled device (CCD). The scan line of data is normalized and calibrated to align the response from individual CCD receptors. The image data signal is converted from analog to digital format on the OCP board. The digital signal is then sent to the host via the SCSI II connection with the host computer.

Indications For Use:

The 960 reads gray information from the image and sends the raw digital data file to a host computer, for use with a Picture Archiving and Communication (PAC) System or teleradiology software package currently in the marketplace as a separately approved third-party software package. The re-user is responsible for detailing the Indications For Use for the PAC System (or teleradiology software package) as a whole, including the 960.

Contraindications

The 960 will be marketed as a component to the software development companies, who will incorporate the 960 into their respective PAC System or teleradiology software package. The software developer will be responsible for detailing the Contraindications for the PAC System (or teleradiology software package) as a whole, including the 960.

Potential Complications

The 960 will be marketed as a component to the software development companies, who will incorporate the 960 into their respective PAC System or teleradiology software package. The software developer will be responsible for detailing the Potential Complications for the PAC System (or teleradiology software package) as a whole, including the 960.

Technological Characteristics of Proposed and Predicate Devices

The proposed 960 has the same basic characteristics as the predicate Howtek Scanmaster DX. The DX is designed to digitize X-ray film or radiographs. In addition, the predicate scanner operates at lower scan rates, less density range, less gray scale resolution and less spatial resolving power. The 960 is superior to all of the listed predicate devices.

Performance Characteristics

The performance testing results for the 960 Film Digitizer demonstrated that the device meets its intended specifications and therefore, meets the requirements necessary for its intended use as a component of a PAC system or teleradiology software package.

Conclusion

Based on the information presented in this Premarket Notification, Howtek, Incorporated believes that the proposed 960 Film Digitizer is substantially equivalent to the Scanmaster DX Film Digitizer. The 960 is equivalent to the predicate film digitizer in regard to its intended use (i.e. it captures X-ray films or radiographs as part of a PAC System or teleradiology software package). The technological characteristics are substantially equivalent in that they are both CCD based film digitizers. The performance characteristics show that the 960 has better range and better resolution that the predicate device, therefore, is more than capable of providing equivalent performance to the DX.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

M. Russell Leonard
Chief Operation Officer
Howtek, Inc.
21 Park Ave.
Hudson, NH 03051

MAY 20 1997

Re: K970908
Howtek 960
Dated: March 5, 1997
Received: March 11, 1997
Regulatory class: Unclassified
Procode: 90 LMA

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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

510(k) Number (if Known): K970908

Device Name: Howtek 960 Film Digitizer

Indications for Use:

The device is used in generating digital signals from medical radiographs. The digital signals are intended for use in PACS and tele-radiology.

(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, ENT,
and Radiological Devices
510(k) Number K970908

Prescription Use: X OR Over-The-Counter Use: