K02 1949

AUG 1 2 2002

Howtek

FOI 510(k) Summary

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: June 12, 2002

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

Device Common / Usual Trade Name: Film Digitizer

Device Trade Name: Fulcrum

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

Predicate or Legally Marketed Devices: Howtek MultiRAD, Film Digitizer

Description of Device:
The device is a transparency film digitizer and paper, charge coupled device (CCD) digitizer that can be used to digitize radiographs or paper reports. The digitizer reads digital gray scale information for each pixel deposits the raw data in the computer. The user interface for the digitizer resides in the applications software. There is no activate button on the digitizer. The activate button is provided trough the digitizer user interface which is part of the third party software package.

Overall the Fulcrum uses a drive, which transport the paper or 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 each individual pixel. The image data signal is converted from analog to digital format by and A to D converter. The Fulcrum creates a digital

image in either 16-bit, 12-bit or 8-bit raw format. The information is transmitted to the computer via USB II.

Indications for Use:
The Howtek Fulcrum Family consists of a transparency film digitizer and paper CCD scanner that is used to digitize radiographs or X-ray film as well as paper reports or doctor's orders. When the Fulcrum is used to digitize radiographic films, the digital image is intended for use in primary, secondary and over reading applications.

The Fulcrum does not include applications specific software (Picture Archiving and Communications (PAC) system, Teleradiology, or Computer Aided Detection (CAD) software). The manufacturer of the application software will determine specific indications for use. These third-party software packages or complete PAC systems are approved separately.

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

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

Technological Characteristics or Proposed and Predicate Device:
The proposed Fulcrum has the same basic characteristics as the predicate Howtek MultiRAD. The MultiRAD was designed to digitize X-ray film or radiographs. In addition, the predicate device operates at lower scan rates, less density range, less gray scale resolution and less spatial resolving power. The Fulcrum is a superior product.

Performance Characteristics:
The performance testing results for the Fulcrum demonstrated that the device meets its intended use specifications and therefore meets the requirements necessary for its intended use as a component of a PAC or Teleradiology system.

Conclusion:

Based on the information presented in this Premarket Notification. Howtek Incorporated believes that the proposed Fulcrum Family of film digitizers is substantially equivalent to the Howtek MultiRAD Family of film digitizers. The Fulcrum family 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 Fulcrum family has the same or better range and resolution as the MultiRAD family. Therefore, the Fulcrum is more than capable of providing equivalent performance than the MultiRAD.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

Mr. W. Scott Parr
CEO
Howtek, Inc.
21 Park Avenue
HUDSON NH 03051

Re: K021949
Trade/Device Name: Fulcrum Family
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: 90 LMA
Dated: June 12, 2002
Received: June 13, 2002

Dear Mr. Parr:

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 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

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Howtek™

Indications for Use

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Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021949