K974535

AUG 17 1998

510(k) Summary of Safety and Effectiveness Information

Marcher Enterprises, Ltd.

DISCAM® DIGITAL IMAGING SYSTEM

Applicant/Manufacturer

Marcher Enterprises, Ltd.
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United Kingdom

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Date of Summary Preparation: October 23, 1997

Device Name

Proprietary Name: Discam® Digital Imaging System
Common Name: Ophthalmic Digital Camera
Classification Name: Camera, Ophthalmic, AC-Powered

Predicate Device

- KOWA OPTIMED, INC.:
  KOWA PROFESSIONAL FUNDUS CAMERA MODELS FX-500
  (K954780, cleared 12/01/95)

- OPHTHALMIC IMAGING SYSTEMS, INC.:
  DFC-512 DIGITAL IMAGING SYSTEM
  (K913929, cleared 11/27/91)

- LASER DIAGNOSTIC TECHNOLOGIES, INC.:
  TOPOGRAPHIC SCANNING SYSTEM
  (K923742, cleared 03/26/93)

- HEIDELBERG ENGINEERING:
  HEIDELBERG RETINA TOMOGRAPH
  (K912891, cleared 09/27/91)

Device Description

The Discam® Digital Imaging System consists of a CCD Stereo Camera that captures stereo images through an image capture board interfaced with a PC with the minimum requirements as follows: 16 Mb RAM, 1 GB Hard Disc, 133 MHz CPU, Windows® 95 OS. The CCD stereo camera and housing is mounted on a standard rise and fall table, along with a standard adjustable patient chin rest.

The patient fixates on fixation lights, (fixed LEDs), and the operator views the image on the PC's monitor. Image capture, which is accomplished in 0.2 seconds, is initiated by pushing a joy stick.

Windows® based software allows basic analysis, (measurement of cup and Disc, cup to Disc ratio), of the captured images, using either our optional analysis software, or third party software with user developed algorithms, and data archiving.

The camera measures 370 mm Depth x 360 mm Height x 108 mm Width. It is powered by a switch mode power supply 100 V to 220 V, 50 Hz to 60 Hz.

Illumination is from a 12 Volt 55 Watt Halogen Lamp. There is no flash.

Intended Use

The Discam® Digital Imaging System is intended to be used as an ophthalmic diagnostic tool, which is complimentary to other accepted diagnostic technologies, to track the progress of glaucoma, relative to monitoring changes in the appearance (size and shape) of the Optic Disc.

Comparison of the Technological Characteristics of the Device to the Predicate.

The determination of the substantial equivalence of the Discam® Digital Imaging System is based upon the following:

- Intended Use
- Operational Characteristics
- Technological Characteristics

A side by side comparison of the characteristics of the Discam® Digital Imaging System to the predicate devices listed above is provided in ***Table 3.***

TABLE 3: COMPARISON OF DEVICE

	Marcher Enterprises, Ltd Discam®	Kowa Optimed Fundus Camera FX-500	La
Intended Use: To view, capture and archive images of the human fundus.	YES	YES	
Ability to measure changes in Optic Disc/Cup size and shape	YES	YES (1)	
Halogen Illumination Source	YES	YES	
Confocal Laser Scanning	NO	NO	
PC Interface	YES	YES (1)	
CCD Camera	YES	YES (2)	
Maximum Field of View	10°	60°	

Note (1): With Optional PC Interface and Software

Note (2): With Optional 35 mm Film Based or Digital CCD

CHARACTERISTICS

ser Diagnostic Technologies TopSS	Heidelberg Eng. Retina Tomograph	Ophthalmic Imaging Systems DFC - 512
YES	YES	YES
YES	YES	YES
NO	NO	YES
YES	YES	NO
YES	YES	YES
NO	NO	YES
30°	30°	60°

Table 3

Testing

- Non-Clinical Testing

  The Discam® Digital Imaging System was tested to assure that the power and luminance levels delivered in every mode of operation were within specification.

- Clinical Testing

  Published data indicate that viewing and capturing images of the Fundus and Optic Nerve Head/Optic Disc with Digital Imaging Systems is safe and effective.

- Conclusions Drawn

  Marcher Enterprises Ltd. believes that the Discam® Digital Imaging System is substantially equivalent to those predicate devices cited above, that any differences are minor, and that these differences do not raise any issue of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 1998

Tim Dawson
Development Director
Marcher Enterprises LTD
Unit 2, Clearview Court, Twyford Road
Rotherwas, Hereford HR2 6JR
UK

Re: K974535
Trade Name: Discam Digital Imaging System
Regulatory Class: II
Product Code: 86 HKI
Dated: July 20, 1998
Received: July 22, 1998

Dear Mr. Dawson:

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/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974535

Device Name: Discam® Digital Imaging System

Indications For Use:

The Discam® Digital Imaging System is intended to be used to evaluate the Optic Disc, (Optic Nerve Head). It is used in the same fashion as a Fundus camera, except that it's field of view is narrower, in order to focus exclusively on the Optic Disc, (Optic Nerve Head). Evaluation of changes in the size and shape of the Optic Disc, (Optic Nerve Head), is useful in monitoring the progress of patients with Ocular Hypertension, and Glaucoma.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Everett R. Beem

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K974535