

12980295

510(k) SUMMARY

MAY 19 1998

MRP Group, Inc.

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

MRP Group, Inc.

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Contact Person: Matthew Carnevale

Date Prepared: January 26, 1998

Name of Device and Name/Address of Sponsor

OphthaVision Imaging System

MRP Group, Inc.
1111 West Lowell Ave.
Haverhill, MA 01832

Common or Usual Name

Camera, Ophthalmic, AC-powered

Classification Name

Camera, Ophthalmic, AC-powered with digital imaging system.

Predicate Devices

Ophthalmic Imaging Systems – DFC Digital Imaging System (K913929)
Midwest Ophthalmic Instruments – ORIMS Digital Angiography (K952480)
Tomey Corporation USA – ImageScape Digital Retinal Image System (K971685)
Topcon – Imagenet Digital Imaging System

Intended Use

The OphthaVision Imaging System is intended to be used to capture, archive and manipulate digital images of the eye obtained through the use of an ophthalmic camera.

Substantial Equivalence

MRP Group, Inc.'s OphthaVision Imaging System, Ophthalmic Imaging System's DFC, Midwest Ophthalmic Instrument's ORIMS, Tomey Corporation's ImageScape and Topcon's Imagenet all have the same intended use: to capture, archive, and manipulate digital images of the eye obtained through the use of an ophthalmic camera. The OphthaVision Imaging System, DFC, ORIMS, ImageScape, and Imagenet also have substantially equivalent technological characteristics. For instance, the OphthaVision, DFC, ImageScape and Imagenet all are equipped with the same Kodak MegaPlus digital camera and 1 gigabyte Jaz drive, and store the files in a TIFF file format.

The OphthaVision Imaging System and the predicate devices are all operated using personal computers with keyboards and a hand-operated mouse. The OphthaVision Imaging System, DFC, ImageScape and Imagenet use the Pentium chip-based personal computers with Microsoft Windows-based software. The OphthaVision Imaging System, DFC, ImageScape and Imagenet systems also have similar storage capabilities and monitors. Minor differences do not raise any new issues of safety or effectiveness because the OphthaVision's storage capabilities are superior to those of Imagenet and DFC's storage capabilities and do not affect the imaging capabilities of the device.

The OphthaVision Imaging System and the predicate devices all have the same basic software functions: image acquisition, analysis, storage and retrieval. The OphthaVision Imaging System and the ImageScape software have nearly identical functions because the OphthaVision Imaging System software was developed to have many of the same functions. The principal difference between the two is the graphical user interface. This difference does not raise any new issues of safety or effectiveness because both systems are graphical user interface systems in which the user clicks a mouse on a button to perform a task. Furthermore, MRP Group, Inc. has performed the software verification and validation. The verification and validation results demonstrate that the device meets the system and software specifications and requirements.

MRP Group Inc.'s OphthaVision Imaging System and the predicate devices are operated in the same manner. The ophthalmologist views the patient's eye through an ophthalmic camera with a digital camera mounted on a C-Mount to capture, archive and manipulate images. The patient is prepared for imaging in accordance with standard ophthalmic procedures and the ophthalmologist operates the joystick to send images to the digital camera in the same manner. For the OphthaVision Imaging System and the predicate devices, images are captured and manipulated using a graphical user interface. The systems software for the various devices also permit the ophthalmologist to print images, view images on the monitor, and archive the images on a removable media drive.

Performance Characteristics

The OphthaVision Imaging System consists of: (1) a digital camera; (2) an imaging board; (3) a personal computer; (4) a monitor; and (5) MRP Group Inc.'s Microsoft Windows based image processing software. The OphthaVision Imaging System is used in ophthalmic procedures such as digital angiography during which the patient's retina is viewed through a slit lamp or a fundus camera. Images are transferred to the OphthaVision Imaging System's imaging board, located in the OphthaVision Imaging System's personal computer and stored in the computer's Random Access Memory (RAM) and hard drive. As the images accumulate, the user downloads the images from the hard drive onto the computer's Jaz drive, a removable media drive, by using the computer keyboard and mouse to manipulate the software interface.

After downloading the images to the Jaz drive, the ophthalmologist may continue to capture images or process the images previously captured and downloaded to the Jaz drive. To further process the images with the OphthaVision Imaging System software, the ophthalmologist can choose options to perform the functions, described in more detail below, for analysis, archival and retrieval of images. In addition, the ophthalmologist may view the images on the monitor or print them on paper.

Each image captured by the digital camera is transferred to the imaging board. The image transfer and processing does not use data compression. The personal computer is an off-the-shelf Performance/VS Pentium Pro computer. The personal computer has MRP Group Inc.'s Microsoft Windows-based image processing software installed which has the capability of saving displaying and archiving images. The software permits the user to manipulate and enhance the image. The image may be magnified, reduced, inverted, flipped or rotated. The user also has the ability to adjust the image's brightness, sharpness and contrast.. The image may be enhanced by shadow, edge trace, and blur functions. The software performs seven image-processing functions: (1) print; (2) extract/delete; (3) save; (4) auto-align; (5) image compare; (6) animate; and (7) stereo imaging.

Images may be printed in portrait or landscape mode depending of the user's selections. Each image may be annotated with patient specific data such as the patient's name, date, and selected eye. The image may be printed on any Microsoft Windows compatible printer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1998

MRP Group, Inc.
Mr. Matthew Carnevale
1111 West Lowell Ave.
Haverhill, MA 01832

Re: K980295
Trade Name: Ophthavision Imaging System
Regulatory Class: II
Product Code: 86 HKI
Dated: May 6, 1998
Received: May 8, 1998

Dear Mr. Carnevale:

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 (Pre-market 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

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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): K980295

Device Name: OPHTHAVISION IMAGING SYSTEM

Indications For Use:

The OphthaVision Imaging System is intended to be used to capture, archive and manipulate digital images of the eye obtained through the use of an ophthalmic camera.

RECEIVED

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FDA/CDRH/ODE/DMC

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

Concurrence of CDRH, Office of device Evaluation (ODE)

Everette A. Bean
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980295

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)