K971685

510(k) SUMMARY

JUN 24 1997

Tomey Corporation

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

Tomey Corporation

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Date Prepared: May 6, 1997

Name of Device and Name/Address of Sponsor

ImageScape Digital Retinal Image System

Tomey Corporation
325 Vassar Street, 2nd Floor
Cambridge, MA 02139

Common or Usual Name

AC-powered ophthalmic camera with digital imaging system.

Classification Name

AC-powered ophthalmic camera

Predicate Devices

Ophthalmic Imaging Systems -- DFC Digital Imaging System (K913929)
Midwest Ophthalmic Instruments -- ORIMS Digital Angiography (952480)
Topcon -- Imagenet Digital Imaging System

Intended Use

The ImageScape is intended to be used to capture, store and manipulate digital images of the retina taken by fundus camera.

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Substantial Equivalence

Tomey's ImageScape, Ophthalmic Imaging Systems DFC, Topcon's Imagenet, and Midwest Ophthalmic Instruments ORIMS have the same intended use: to capture, store, and manipulate digital images of the retina taken by a fundus camera. The ImageScape, DFC, Imagenet, and ORIMS digital imaging systems also have substantially equivalent technological characteristics. For instance, the ImageScape and DFC both are supplied with the same Kodak MegaPlus digital camera and 1 gigabyte Jaz drive, and also store the files in a TIFF file format.

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

The ImageScape and the predicate devices have the same software functions: image acquisition, analysis, storage, and retrieval. The ImageScape and ORIMS software have almost identical functions because the ImageScape software was developed to have many of the same functions. The principal difference between the software is the operating system. The ImageScape is based on the Windows 95 operating system and the ORIMS is based on the Macintosh operating system. This difference does not raise any new issues of safety or effectiveness because both systems are icon-driven systems in which the user clicks a mouse on an icon to perform a task. Furthermore, Tomey has performed the software verification and validation. The verification and validation results demonstrate that the device meets the system and software specifications and requirements.

Tomey's ImageScape and the predicate devices are operated in the same manner. The ophthalmologist views the patient's retina through a slit lamp and uses a fundus camera with a digital camera mounted on a C-Mount to capture, store, and manipulate retinal images. The patient is prepared for retinal 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 Tomey System and the predicates, images are captured and manipulated using icon-driven computer interfaces. 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.

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Performance Characteristics

The ImageScape consists of: (1) a digital camera; (2) an imaging board; (3) a personal computer; (4) a monitor; and (5) Tomey's Windows-based image processing software. The ImageScape is used during ophthalmic procedures such as digital angiography during which the patient's retina is viewed through a slit lamp with a fundus camera. Images are transferred to the ImageScape's imaging board, located in the ImageScape'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 operate the icons.

After downloading the images to the Jaz drive, the ophthalmologist can then continue to capture more retinal images or process the images already captured and downloaded on the Jaz drive. To further process the images with the ImageScape software, the ophthalmologist operates the keyboard or mouse. As the software is Windows 95-based, the ophthalmologist can click icons to perform the functions, described in more detail below, for analysis, storage, and retrieval of images. In addition, the ophthalmologist can view the images on the monitor's screen or print them on paper.

The 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 is loaded with Tomey's Windows-based image processing software that is used to save, display, and store the images. The software permits the user to manipulate and enhance the image. The image can be manipulated by zooming in or out, inverting, flipping, or rotating the image. It also can be manipulated by adjusting the brightness and contrast and sharpening the image. The image can be enhanced by shadow, edge trace, and blur functions. The software has seven image-processing functions: (1) print; (2) extract/delete; (3) save; (4) auto-align; (5) image comparison; (6) animation; and (7) stereo image.

The print function has the option of allowing the user to create a montage window for printing landscape format images. It also permits the user to annotate the images with the patient's name, date, and selected eye. The image is printable to any printer configured to work with Windows 95.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1997

Tomey Corporation USA
c/o Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
555 Thirteenth St., N.W.
Washington, D.C. 20004

Re: K971685
Trade Name: ImageScape Digital Retinal Image System
Regulatory Class: II
Product Code: 86 HKI
Dated: May 6, 1997
Received: May 7, 1997

Dear Mr. Holstein:

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) 594-4613. 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): K971685

Device Name: ImageScape

Indications For Use:

The ImageScape is intended to capture, store, and manipulate digital images of the retina taken by a fundus camera.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

AM Williams

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K971685

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

(Optional Format 1-2-96)