3/26/99

K990205

EyeTel's Digiscope Ophthalmic Camera

Name of Device	Digiscope ophthalmic camera
Common or Usual Name	Camera, Ophthalmic (AC Powered)
Classification Name	Ophthalmic camera (per 21 C.F.R. 866.1120)
Product Code	HKI
Submitter	EyeTel Imaging. Inc. 15078 Stillfield Place Centreville, Virginia 20120
Phone:	(703) 803-8584
Facsimile:	(703) 815-3721
Contact Person:	Kevin T. Quinn
Date Prepared:	

Predicate Devices

Trade name	Manufacturer	510(k)
ImageScape Digital Retinal Imaging System	Tomey Corporation	K971685
ImageNet Digital Ophthalmic Imaging System	Topcon	K870039

Intended Use

EyeTel's ("EyeTel") Digiscope, the Tomey Corporation ImageScape Digital Retinal Image System and the Topcon, Inc. ImageNet Digital Imaging System and are intended to capture and store images of the retina taken by a fundus camera. The Digiscope is an automated imaging device of the fundus that is intended to capture, store, and transmit images of the fundus using lossless compression to a distant location for display. The Digiscope requires minimal operator training and intervention during the imaging process. It is indicated for individuals where examination of the fundus for pathologies is requested. The predicate devices are likewise comprised of fundus cameras and computer hardware/software systems intended to capture, store, and transmit images of the fundus. Thus, the Digiscope ophthalmic camera has the same intended use and indications as these predicate devices.

Substantial Equivalence

The EyeTel Digiscope, Tomey Corporation's ImageScape system, and the Topcon ImageNet system have the same intended use: to capture, store, and transmit images of the fundus. The Digiscope and the predicate devices have similar principles of operation and technological characteristics. Each of the devices is an ophthalmic camera. The user views the patient's retina through a slit lamp or fundus camera. A light source is then used to generate images of the retina which are captured by the camera. The images are then digitized and

stored. Successive images are taken to permit viewing of a larger area of the retina. The stored images may be viewed on a monitor.

The technological differences between the Digiscope ophthalmic camera and its predicate devices are the degree of automation of Digiscope's fundus camera and its targeting and focusing, the storage system, and the media on which the images may be captured (digital electronic display *vs.* film or printed image). However, these differences do not raise any new questions of safety or effectiveness. The Digiscope uses a dedicated camera and an automated illumination system, while the predicate devices use non-dedicated fundus cameras or slit lamps that rely on manual targeting and focusing. In each device, the data is acquired in a non-compressed format and is capable of being stored in individual image data files. The minor differences in data storage are the type of storage media. For the Digiscope and the ImageScape, the data is stored in an uncompressed state on the hard drive of the computer system. The ImageScape system then permits downloading of the data with compression to a 1 gigabyte JAZ drive, while the Digiscope permits transmission of the data via lossless compression to remote locations for display. The Topcon ImageNet utilizes a read/write CD-ROM recorder to store the images.

Performance Characteristics

The Digiscope Ophthalmic camera consists of: (1) a video camera; (2) an imaging system; (3) a computer with image acquisition and hardware control capabilities; (4) a monitor; and (5) EyeTel's Digiscope software. The Digiscope is intended to capture, store, and transmit images of the fundus and is indicated for use as an ophthalmic camera for individuals where examination of the fundus for pathologies is requested. The images of the fundus are digitized, stored on the Digiscope's hard drive, and transmitted via lossless compression for display at distant locations.

The Digiscope's user/software interface allows the images of the eye to be acquired, monitored, stored, and retrieved. Data is input into the Digiscope software via a touchscreen. Imaging, focusing, and camera orientation in relation to the retina are controlled by the software with verification and monitoring by the user. The software allows the user to monitor the image capture process and verify that the device is operating appropriately.

The image of the fundus is acquired by the Digiscope and stored in individual image data files in an uncompressed state on the hard drive of the computer system and displayed electronically. The images may then be transmitted via lossless compression to distant locations for display using a modem and standard telecommunications connections.

Conclusion

The Digiscope has the same intended use and indications, and very similar principles of operation and technological characteristics as the Tomey Corporation ImageScape Digital Retinal Image System and the Topcon, Inc. ImageNet Digital Imaging System. The minor differences between the Digiscope and the predicate devices do not raise any new questions of safety or effectiveness. Thus, the EyeTel Digiscope ophthalmic camera is substantially equivalent to legally marketed ophthalmic cameras.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 1999

Mr. Kevin T. Quinn
President
EyeTel Imaging, Inc.
15078 Stillfield Place
Centreville, VA 20120

Re: K990205
Trade Name: Digiscope Ophthalmic Camera
Regulatory Class: II
Product Code: 86 HKI
Dated: March 16, 1999
Received: March 17, 1999

Dear Mr.Quinn:

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): K990205

Device Name: EyeTel Digiscope Ophthalmic Camera

Indications for Use:

The Digiscope is indicated for use as an ophthalmic camera for individuals where examination of the fundus for pathologies is requested.

(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 Ophthalmic Devices
510(k) Number K990205

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)