SEP 2 6 2001 K011877

Carl Zeiss Jena's FF450 plus VISUPAC System 510(k) Summary

Name of Device	FF450 plus VISUPAC System
Common or Usual Name	Fundus Imaging Device (Camera)
Classification Names	Ophthalmic Camera, AC-Powered and Accessories (21 C.F.R. § 886.1120)
Product Codes	HKI
Submitter	Carl Zeiss Jena GmbH Ophthalmic Instrument Division Germany
Phone:	011 49 3641 64 2474
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Contact Person:	Michael Giebe
Date Prepared:	May 18, 2001

Predicate Devices

Trade Name	Manufacturer
IMAGEnet Digital Ophthalmic Imaging System	Topcon Inc
ImageScape Digital Retinal Imaging System	Tomey Corporation

Intended Use

The FF450 plus VISUPAC system is intended to capture, display, store, and manipulate images of eye, especially the retina area, as well as surrounding areas, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

Substantial Equivalence

The FF450 plus VISUPAC system and the predicate devices have the same intended use and indications. All of these devices are ophthalmic camera and image management systems intended to capture, display, store, and manipulate images of eye, especially the retina area, as well as surrounding areas, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

To acquire these images the FF450 plus VISUPAC system and the predicate devices use monocular ophthalmic cameras that function according to the same principles of operation and technological characteristics. Light from an

external light source is used to generate images of the eye which are captured using the fundus camera, displayed on a monitor, stored on electronic media by a computer system, and manipulated by the user via the system software. The question of safety and effectiveness, namely - does each system permit the acquisition, manipulation, storage, and retrieval of images, is the same for the FF450 plus VISUPAC system and the predicate devices despite minor differences in the way in which each device manipulates or stores the image.

Conclusion

Carl Zeiss Jena's FF450 plus VISUPAC system has the same intended use and indications for use, and similar principles of operation and technological characteristics as the Topcon, Inc. IMAGEnet Digital Ophthalmic Imaging System and Tomey Corporation ImageScape Digital Retinal Imaging System. The minor technological differences between the FF450 plus VISUPAC system and the class II predicate devices, including the degree of user support and storage media, do not raise new questions of safety or effectiveness. Thus, the FF450 plus VISUPAC system is substantially equivalent to legally marketed devices intended to capture, display, store, and manipulate images of eye, especially the retina area, as well as surrounding areas, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2001

Johnathan S. Kahan
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004 -1109

Re: K011877
Trade/Device Name: FF450 Plus Funds Camera and VISUPAC Digital Image Archiving System
Regulation Number: 21 CFR 886.1120; 21 CFR 892.2010; 21 CFR 892.2020
Regulation Name: Camera, Ophthalmic, AC-powered; Device, Storage, Images, Ophthalmic; Device, Communication, Images, Ophthalmic
Regulatory Class: Class II; Class I; Class I
Product Code: HKI; NFF; NFG
Dated: June 15, 2001
Received: June 15, 2001

Dear Mr. Kahan :

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 such 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 Section 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 21 CFR Part 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" (21CFR 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,

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

510(k) Number (if known): K011877

Device Name: FF450 plus Fundus Camera and VISUPAC System

Indications for Use:

The FF450 plus VISUPAC system is intended to capture, display, store, and manipulate images of eye, especially the retina area, as well as surrounding areas, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dexiu Lin 9-28-2001

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011877

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)