K021787

JUN 21 2002

Carl Zeiss Jena GmbH, Ophthalmic Instruments Division

VISUCAM^{lite} Fundus Camera
Special 510(k) – Device Modification Summary

Name of Unmodified Device:	FF450plus Fundus Camera and VISUPAC Digital Image Archiving System
Name of Modified Device:	VISUCAM^{lite} Fundus Camera
Common or Usual Name:	Fundus Imaging Device (Camera) and Accessories
Classification Name:	Camera, Ophthalmic, AC-powered; Device, Storage, Images, Ophthalmic; Device, Communication, Images, Ophthalmic
Product Code:	HKI, NFF, NFG
Submitter:	Carl Zeiss Ophthalmic Systems Inc. Hacienda Drive Dublin, CA 94568, USA Tel.: (925) 557 4193 Fax: (925) 557 4504
Contact Person:	Nancy E. Funston
Consultant:	Jonathan S. Kahan Partner Hogan & Hartson L.L.P. 555 Thirteenth Street, N.W. Washington, DC 20004-1109 Tel.: (202) 637-5794 Fax: (202) 637-5910
Date Prepared:	May 24, 2002

Intended Use:

The VISUCAM^{lite} Fundus Camera is intended to capture, display and store 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.

Device Modification:

Zeiss' VISUCAM^{lite} model is designed for a more general ophthalmology practice than the VISUPAC Fundus Camera. Therefore the VISUCAM^{lite} is a more compact model of the VISUPAC Fundus Camera and designed for less specialized ophthalmic practices. Certain technical specifications for the VISUCAM^{lite} have been modified because the VISUCAM^{lite} model is not designed for indocyanine angiography and imaging that requires very high image resolution, different field angles, and corresponding viewing fields. Specifically, Zeiss has modified the cleared device to: (1) reduce the light intensity; (2) eliminate specific device equipment like an external power supply unit, an external computer with storage and archiving module, and different external dedicated electronic cameras as well as dedicated photographic equipment; (3) reduce the available viewing angles and image resolution; and (4) revise the device software to accommodate less demanding image processing requirements.

Conclusion

Side-by-side comparisons of the VISUCAM^{lite} Fundus Camera versus the predicate FF450^{plus} Fundus Camera and VISUPAC Digital Image Archiving System as approved with the notification K011877 demonstrate that both devices are virtually identical with exception of minor variations that are detailed introduced. Finally, we conclude based on our review and assessment of the similarities and the differences the new VISUCAM^{lite} Fundus Camera does not affect any question for safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carl Zeiss Ophthalmic System Inc.
c/o Johnathan S. Kahan
Partner
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004 -1109

JUN 21 2002

Re: K021787
Trade /Device Name: VISUCAM^{lite} Fundus Camera
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: May 24, 2002
Received: May 30, 2002

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,

A. Ralph Rosenthal

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): K021787

Device Name: **VISUCAM^{lite}**

Indication for Use: The VISUCAM^{lite} Fundus Camera is intended to capture, display and store 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.

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Concurence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

Dexin Shu 6-14-2002

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021787

Prescription Use ✓
(Per 21 CFR 801.109)