K033123

APR 2 0 2004

510(k) Summary
Carl Zeiss Meditec Incorporated
***STRATUS*OCT™ with RNFL & Macula Normative Database**

This 510(k) summary for the *STRATUS*OCT™ with RNFL & Macula Normative Database is submitted in accordance with the requirements of SMDA 1990 and 21 C.F.R § 807.92.

GENERAL INFORMATION

Manufacturer:
Carl Zeiss Meditec Inc.
5160 Hacienda Drive
Dublin, California 94568
(925) 557-4353 (phone)
(925) 557-4481 (fax)
Est. Reg. No. 2918630

Contact Person:
R. Michael Crompton
Vice President, Regulatory / Clinical Affairs
and Quality Assurance

DEVICE DESCRIPTION

Classification: Class II

Trade Name: *STRATUS*OCT™ with Retinal Nerve Fiber Layer and Macula Normative Database

Generic/Common Name: Ophthalmoscope (21 CFR § 886.1570)
Ultrasonic pulsed echo imaging system (21 CFR § 892.1560)

PREDICATE DEVICE

(1) *STRATUS*OCT™ with Retinal Nerve Fiber Layer Normative Database

INTENDED USE

The *STRATUS*OCT™ is a high resolution tomographic device for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer, macula, and optic disk. The STRATUSOCT™ with Retinal Nerve Fiber Layer ("RNFL") & Macula Normative Database is a quantitative tool for the comparison of retinal nerve fiber layer and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to, macular edema, central serous retinopathy, and glaucoma.

DEVICE DESCRIPTION

The *STRATUS*OCT™ with RNFL & Macula Normative Database is a microprocessor-based low-coherence digital instrument employing low coherence interferometry to generate images of internal ocular tissue microstructures. The device measures optical reflections or backscatter from tissue using a scanning optical beam. Results obtained for the Retinal Nerve Fiber Layer and the Macula can be compared to a database of known normal human patients.

SUBSTANTIAL EQUIVALENCE

The *STRATUS*OCT™ with RNFL & Macula Normative Database is substantially equivalent to the predicate device identified previously. The *STRATUS*OCT™ with RNFL & Macula Normative Database is substantially equivalent to the predicate device with regard to intended use, operating principle, function, and materials.

Clinical evaluation performed on the *STRATUS*OCT™ with RNFL & Macula Normative Database supports the expanded indications for use statement and demonstrates the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness with respect to ophthalmoscopes and ultrasonic pulsed echo imaging systems.

CLINICAL EVALUATION

Clinical data was collected on a statistically significant number of normal human patients and analyzed to support the inclusion of the Macula Normative Database in the *STRATUS*OCT™.

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the *STRATUS*OCT™ with RNFL & Macula Normative Database to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2007

Carl Zeiss Meditec, Inc.
c/o Ms. Judith A. Brimacombe
5160 Hacienda Drive
Dublin, CA 94568

Re: K030433 and K033123
Trade/Device Name: STRATUS$_{OCT}$™ with Retinal Nerve Fiber Layer (RNFL) & Macula Normative Database
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: February 7, 2003 and September 26, 2003
Received: February 10, 2003 and September 30, 2003

Dear Ms. Brimacombe:

This letter updates our substantially equivalent letters of May 1, 2003 and April 20, 2004, respectively.

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 (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 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 continue 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Evenette V Beers PhD

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K033123

Device Name: STRATUSOCT™ with RNFL & Macula Normative Database

Indications for Use: The STRATUSOCT™ is a high resolution tomographic device for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging and measurement of the retina, retinal nerve fiber layer, macula, and optic disk. The STRATUSOCT™ with Retinal Nerve Fiber Layer ("RNFL") & Macula Normative Database is a quantitative tool for the comparison of retinal nerve fiber layer and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to, macular edema, central serous retinopathy, and glaucoma.

(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 Ear,
Nose and Throat Devises

510(k) Number K033123

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 C.F.R. § 801.109)