SEP 3 0 2005

510(k) Summary K051789
Carl Zeiss Meditec Incorporated

This 510(k) summary for the Visante OCT is submitted in accordance with the requirements of SMDA 1990 and 21 C.F.R § 807.92.

GENERAL INFORMATION

Manufacturer: Carl Zeiss Meditec Inc.
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Dublin, California 94568
(925) 557-4616 (phone)
(925) 557-4481 (fax)
Est. Reg. No. 2918630

Contact Person: Judith A. Brimacombe, MA
Director, Regulatory / Clinical Affairs

DEVICE DESCRIPTION

Classification: Class II

Trade Name: Visante™ OCT

Generic/Common Name: Device, Analysis, Anterior Segment; Ophthalmoscope

PREDICATE DEVICES

(1) *STRATUS*OCT™ with Retinal Nerve Fiber Layer Normative and Macula Database
(2) Orbscan™ II

INTENDED USE

The Visante OCT is intended for use in the viewing and imaging of anterior segment ocular structures.

INDICATIONS FOR USE

The Visante™ OCT is a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging and measurement of ocular structures in the anterior segment, such as corneal and LASIK flap thickness.

DEVICE DESCRIPTION

The Visante OCT is computerized instrument that acquires and analyzes cross-sectional tomograms of the anterior eye segment (cornea, anterior chamber, iris and the central portion of the lens). It employs non-invasive, non-contact, low-coherence interferometry to obtain these high-resolution images. Using this non-invasive optical technique, Visante OCT produces high-resolution cross-sectional tomograms of the eye without contacting the eye.

SUBSTANTIAL EQUIVALENCE

The Visante OCT is substantially equivalent to the predicate devices identified previously. The Visante OCT is substantially equivalent to the predicate devices with regard to intended use, operating principle, function, and materials.

Clinical evaluation performed on the Visante OCT supports the indications for use statement and demonstrates the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness with respect to anterior segment analysis devices and ophthalmoscopes.

CLINICAL EVALUATION

Clinical data was collected on a statistically significant number of normal human patients and analyzed to support the indications for use statement for the Visante OCT.

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the Visante OCT 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: K051789
Trade/Device Name: Visante™ OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: July 1, 2005
Received: July 7, 2005

Dear Ms. Brimacombe:

This letter updates our substantially equivalent letter of September 30, 2005.

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.

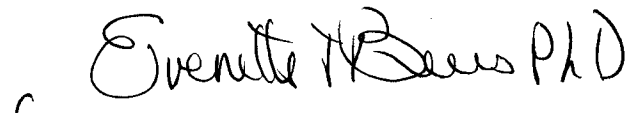
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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): K051789

Device Name: Visante™ OCT

Indications for Use: The Visante™ OCT is a non-contact, high resolution tomographic and biomicroscopic device indicated for the *in vivo* imaging and measurement of ocular structures in the anterior segment, such as corneal and LASIK flap thickness.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Butterfield, DOED

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