5. 510(k) SUMMARY

SEP – 2 2009

510(k) Owner:

Topcon Corporation.
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174-8580
Phone Number: +81-3-3558-2566
FAX Number: +81-3-3965-6532

U.S. Facility:
Topcon Medical Systems, Inc.
37 West Century Road
Paramus, New Jersey 07652
Phone Number: (201) 599-5153
FAX Number: (201) 599-5240

Contact person:

Takao Sugawara
Manager
TOPCON CORPORATION
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174-8580
Phone Number: +81-3-3558-2566
FAX Number: +81-3-3965-6532

Date: August 6, 2009

Trade Name: 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-2000

Common names: OPTICAL COHERENCE TOMOGRAPHY

Classification Name: Tomography, Optical coherence
21CFR886.1570 Ophthalmoscope

Product Code: OBO

510(k) Number: K092470

Identification of a Legally Marketed Predicate Device

The 3D OCT-2000 is substantially equivalent to the 3D OCT-1000 (K06388), 3D OCT-1000 for Measurement of Retinal Thickness (K072971) and 3D OCT-1000 MARK II (K083316). All of those predicate devices are marketed by TOPCON CORPORATION and FDA Product Code is OBO.

General Description

The Topcon 3D OCT-1000 is a non-contact ophthalmic imaging system for the viewing and axial cross sectional imaging of posterior ocular structures. It is used for *in vivo* imaging of the retina, retinal nerve fiber layer and optic disc. 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 and central serous retinopathy.

The 3D OCT-1000 for Measurement of Retinal Thickness is identical to the 3D OCT-1000 with the exception of the addition of a new software module allowing for the measurement of retinal thickness.

The technological characteristics of the 3D OCT-1000 MARK II are the identical for the 3D OCT-1000, with the exception that during OCT imaging, the scan beam for the 3D OCT-1000 is delivered as continuous wave (CW) light; whereas, it is delivered as pulsed lighting in the 3D OCT-1000 MARK II.

The 3D OCT-2000 has same intended use and indication for use as the 3D OCT-1000, 3D OCT-1000 for Measurement of Retinal Thickness and 3D OCT-1000 MARK II. The technological characteristics are the identical.

During OCT imaging, the scan beam for the 3D OCT-2000 is delivered as pulsed lighting same as 3D OCT-1000 MARK II. The PC software of the 3D OCT-2000 has same functions of the PC software of the 3D OCT-1000 and 3D OCT-10000 MARK II and also the PC software of the 3D OCT-2000 has same functions for the measurement of retinal thickness of the 3D OCT-1000 for Measurement of Retinal Thickness.

Intended Use / Indication for Use

The 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-2000 is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in vivo viewing, axial, cross-sectional and three-dimensional imaging and measurement of posterior ocular structures including retina, retinal nerve fiber layer, macula, and optic disk. It is intended for use as a diagnostic device to aid in the detection and management of

ocular diseases affecting the posterior segment of the eye.

Patient profiles

This instrument has not been designed to apply to infants. Use this instrument meticulously for infants.

This instrument is contraindicated in the following patients.

- The patient who has a history of photosensitivity.
- The patient who has just received the treatment of photodynamic therapy (PDT) (For the prohibition period, refer to the package insert of the taken light-sensitive substance.)
- The patient who takes the medicine that can cause the photosensitivity as its side effect.

Use this instrument meticulously for the following patients.

- The patient who has epidemic kerato conjunctivitis, or any other infectious disease.
- The patient who has taken the medicine that can cause the photosensitivity as its side effect.
- The patient who is at high risk for the optical radiation hazard, such as aphakic eye, infant, and the patient who diminishes the sensibility to light by fundus disease.

Performance Data

Software validation testing (with PC software) and image capture testing were performed on the 3D OCT-2000. And also, the test results for the 3D OCT-2000 demonstrated sufficient equivalence with measuring the retinal thickness from the 3D OCT-1000 for Measurement of Retinal Thickness.

The results of performance testing and software validation testing did not raise any issues on the safety or effectiveness of the device.

Basis of Substantial Equivalence

The 3D OCT-2000 is substantially equivalent to the 3D OCT-1000 (K06388), 3D OCT-1000 for Measurement of Retinal Thickness (K072971) and 3D OCT-1000 MARK II (K083316) marketed by Topcon. The 3D OCT-2000 and predicate devices mentioned above have same FDA Product Code OBO, and regulation 21CFR§886.1570 (Ophthalmoscope) in technological characteristics, engineering design and specifications, software design and specifications, optical coherence tomography light source classification (IEC 60825-1) and intended use.

Standards for testing

TOPCON conducted several tests for the 3D OCT-2000 to ascertain conformity to following standards.

IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991; Amendment 2, 1995
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests Edition 3:2007
IEC 60825-1	Safety of laser products - Part 1: Equipment classification and requirements, 1993; Amendment 1, 1997; Amendment 2, 2001
ISO 15004-1:2006	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
ISO 15004-2:2007	Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection

No deviation or adaptation is made in the use of above mentioned standards.
See Attachment 1 for IEC 60601-1 Test Reports and IEC 60601-1-2 Test Reports.
See Attachment 2 for IEC 60825-1 Verification Reports
See Attachment 3 for ISO 15004-1:2006 evaluation results
See Attachment 4 for ISO 15004-2:2007 evaluation results
See Attachment 5 for Form FDA 3654 of each standard.

The 3D OCT-2000 has no component which contacts with blood, bodily fluid or mucous membrane. Therefore, Biocompatibility tests were not performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Topcon Corporation
c/o Takao Sugawara
Manager
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174-8580

SEP - 2 2009

Re: K092470
Trade/Device Name: 3D Optical Coherence Tomography 3D OCT-2000
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: August 6, 2009
Received: August 12, 2009

Dear Mr. Sugawara:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092470

Device Name: 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-2000

Indications for Use:

The 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-2000 is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in vivo viewing, axial, cross-sectional and three-dimensional imaging and measurement of posterior ocular structures including retina, retinal nerve fiber layer, macula, and optic disk. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases affecting the posterior segment of the eye.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

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

510(k) Number K092470