DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 3, 2017

Topcon Corporation
% Jonathan S. Kahan
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K170164
Trade/Device Name: 3D OCT-1 Maestro
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HKI
Dated: February 3, 2017
Received: February 3, 2017

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement on last page

510(k) Number *(if known)*

K170164

Device Name

3D OCT-1 Maestro

Indications for Use *(Describe)*

The Topcon 3D OCT-1 Maestro is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.

The 3D OCT-1 Maestro 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 disc as well as imaging of anterior ocular structures.

It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The 3D OCT-1 Maestro is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

TOPCON 3D OCT-1 Maestro

Submitter

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Japan

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Contact Person: James Lorkowski, Regulatory Affairs Manager

Date Prepared: March 2, 2017

Name of Device: 3D OCT-1 Maestro

Common or Usual Name: Optical coherence tomography, AC-powered ophthalmic camera

Classification Name: 21 C.F.R. § 886.1570, *Ophthalmoscope*

Regulatory Class: Class II

Product Code: OBO, HKI

Predicate Device: Topcon Corporation's 3D OCT-1 Maestro (K161509)

Device Description

The 3D OCT-1 Maestro with new line CCD is a non-contact, high-resolution, tomographic and bio-microscopic imaging system that combines optical coherence tomography (OCT) and fundus camera technology, along with various quantitative measurement and other data analysis functionalities. The device consists of the instrument body (main unit, chin-rest unit, and power supply base), software (to operate the instrument and to process the analysis functions), and various accessories. The software incorporates a number of safety features to detect errors during use and interrupt device functions as needed when an error is identified.

The only patient-contacting materials in the device – silicone rubber, Acrylonitrile-butadiene styrene resin (ABS), and polyamide resin (PA) – are classified per FDA's guidance on ISO 10993-1 as limited-duration contact with the patient or operator's intact skin. These are the same materials as were incorporated in the patient-contacting pieces of the predicate device.

The device is re-usable and is not supplied sterile; cleaning instructions are provided in the labeling and are essentially the same as those for the predicate device. The device is AC-powered.

The principles of operation of the modified Maestro are almost identical to those of the cleared predicate. The optical pathway from a patient's eye to the objective lens is shared between the OCT and fundus camera parts, while the optical pathways from the objective lens onwards into the device are prepared separately and independently for the OCT and fundus camera functionalities. Because the fundus photographs and OCT images captured by the device use different system components in a sequential manner, the combination of the two image systems in a single device does not present a risk that one image type could adversely impact the capture of the other image type.

To operate the device, the user first registers a patient or selects an already registered patient with the PC software and presses the "capture" button. The user then selects a scan protocol and an eye (left or right), and the device automatically adjusts to align, focus, and optimize the image and then captures both an OCT image and a fundus image of the selected protocol. Subsequently, the pair of images is transferred to the PC and displayed for data analysis; automatic and/or manual quantitative measurement functions, as well as other data management and assessment functions, are available for different types of scans and photography protocols. The anterior segment/fundus tomogram is obtained using the principle of optical interference, where emitted light is separated into two portions that are reflected back to the fiber coupler and re-joined, forming a low interference wave that is then separated by the diffraction grating and converted into electric signal by the line CCD. This signal is then processed to observe, photograph and record the tomogram.

Intended Use/Indications for Use

The 3D OCT-1 Maestro with new line CCD has the following intended use and indications for use:

The Topcon 3D OCT-1 Maestro is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions.

The 3D OCT-1 Maestro 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 disc as well as imaging of anterior ocular structures.

It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The 3D OCT-1 Maestro is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.

These indications for use are identical to those of the cleared predicate device.

Summary of Technological Characteristics

Optical coherence tomography and fundus photography are the key technological principles for both the subject and predicate devices, as described above. At a high level, the subject and predicate devices both consist of a combined optical system of OCT, fundus camera (IR or Red-free image), and anterior observation camera.

The following technological differences exist between the subject and predicate devices:

- Replacement of the current line CCD component with an equivalent part produced by a different supplier and with slightly different specifications;
- Modification of lens unit and lens configuration in fundus illumination optical system with slightly different specifications, though the specifications of the total illumination system are the same; and

- Other minor changes:
    - Hardware/Firmware changes to improve workability and quality and to reduce cost by utilizing more effective EMC measures;
    - Software modifications to reflect the hardware/firmware changes, update routine operational elements, and enhance the user experience;
    - Labeling changes to conform to unique device identification ("UDI") requirements; and
- Production/manufacturing changes to improve product assembly.
- Several minor changes the company determined could not significantly affect safety or effectiveness.

A table comparing the key features of the subject and predicate devices is provided below.

Purpose of 510(k)

The purpose of this 510(k) is to modify the 3D OCT-1 Maestro device by replacing the line CCD component and to provide a record of the other minor hardware, software, labeling, and processing modifications that have been implemented to enhance quality and workability.

Performance Data

The company performed bench testing – including light safety, electromagnetic compatibility, and software verification and validation – to confirm that the modified 3D OCT-1 Maestro functions equivalently to the predicate 3D OCT-1 Maestro. Where relevant, the testing was conducted in conformance with the following FDA-recognized, voluntary consensus standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 And A2:2010(R)2012 - Medical electrical equipment, Part1: General requirements for basic safety and essential performance, Version Ed. 3.1, 2005
- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- ISO 15004-1, Ophthalmic instruments – Fundamental requirements and test methods Part1: General requirements applicable to all ophthalmic instruments, 2006
- ISO 15004-2, Ophthalmic Instruments – Fundamental requirements and test methods Part2: Light hazard protection, 2007
- ISO 10940, Ophthalmic instruments – Fundus cameras, 2009
- ANSI/AAMI 62304, Medical Device Software – Software Life Cycle Processes, 2006.

In all instances, the 3D OCT-1 Maestro with new line CCD functioned as intended and produced the expected results, demonstrating that the safety and effectiveness profile of the modified device is the same as that of its predicate.

Conclusions

The 3D OCT-1 Maestro with new line CCD is as safe and effective as the previously cleared 3D OCT-1 Maestro (K161509). The modified device has the same intended use, indications for use, and principles of operation as its predicate. In addition, the minor technological differences between the 3D OCT-1 Maestro with new line CCD and the predicate raise no

new issues of safety or effectiveness. Performance data demonstrate that the modified device is as safe and effective as the predicate Maestro device. Thus, the 3D OCT-1 Maestro with new line CCD is substantially equivalent.

Substantial Equivalence Comparison Table

	Subject Device: 3D OCT-1 Maestro with new Line CCD	**Predicate: 3D OCT-1 Maestro(K161509)**
510(k) Number	K170164	K161509
Intended Use / Indications for Use	The Topcon 3D OCT-1 Maestro is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions. The 3D OCT-1 Maestro 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 disc as well as imaging of anterior ocular structures. It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The 3D OCT-1 Maestro is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.	The Topcon 3D OCT-1 Maestro is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions. The 3D OCT-1 Maestro 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 disc as well as imaging of anterior ocular structures. It also includes a Reference Database for posterior ocular measurements which provide for the quantitative comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. The 3D OCT-1 Maestro is indicated for use as a diagnostic device to aid in the diagnosis, documentation and management of ocular health and diseases in the adult population.
Light Source	Spectral domain OCT (SD-OCT) using a superluminescent diode (SLD) with center wavelength 840 nm.	Spectral domain OCT (SD-OCT) using a superluminescent diode (SLD) with center wavelength 840 nm.
Analysis	For posterior: - Retinal layer segmentation - Thickness calculation - Optic disc analysis For anterior: NA	For posterior: - Retinal layer segmentation - Thickness calculation - Optic disc analysis For anterior: NA
Observation	Light source - IR LED Camera - CMOS camera	Light source - IR LED Camera - CMOS camera