April 10, 2024

Topcon Corporation
℅ Lena Sattler
President
Orasi Consulting
226 1st Street
Bonita Springs, Florida 34134

Re: K233561
Trade/Device Name: 3D Optical Coherence Tomography (3D OCT-1(type: Maestro2))
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HKI
Dated: November 6, 2023
Received: November 6, 2023

Dear Lena Sattler:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.
Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233561

Device Name
3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)

Indications for Use *(Describe)*
The TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) is a noncontact, 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 TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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 TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2)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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
TOPCON CORPORATION
Traditional 510(k) for:
3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2) with System linkage software

GENERAL INFORMATION

Submitter's information:
TOPCON Corporation
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, 174-8580, Japan

Contact person:
Lena Sattler
President, Orasi Consulting
Phone: 440-554-3706
Email: lena@orasiconsulting.com

Date Prepared:
April 5, 2024

DEVICE INFORMATION

SUBJECT DEVICE:

Name of Device:	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)
Device Class:	Class II
Classification Name:	21 C.F.R. § 886.1570, Ophthalmoscope 21 C.F.R. §886.1120, Ophthalmic camera
Product Code:	OBO, HKI

PREDICATE DEVICE:

Company	Topcon Corporation
Device	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)
510(k) No.	K231222

Brief Device Description

3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)
3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2) with System linkage software (herein referred to as "Maestro2") is a non-contact ophthalmic device combining spectral-domain optical coherence tomography (SD-OCT) with digital color fundus photography. Maestro2 includes an optical system of OCT, fundus camera (color, IR and Red-free image), and anterior observation camera. The color fundus camera acquires color images of the posterior segment of the eye under mydriatic or non-mydriatic conditions. Maestro2 is used together with IMAGEnet6 by connecting via System linkage software which is a PC software installed to off the shelf PC connected to Maestro2. The remote operation function is not intended to be used from any further distance (e.g., operation from different rooms or different buildings) other than social distancing recommendations.

Intended Use / Indications for Use

3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)
The TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) is a noncontact, 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 TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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 TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2)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.

Performance Data

It has been verified that the subject device functions as intended by tests or evaluations based on the following FDA-recognized, voluntary consensus standards, and the in-house test specification. The results of the testing support substantial equivalence by demonstrating that the device performs as intended and complies with the same standards as the predicate device.

FDA-recognized, voluntary consensus standards	
IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment - Part 1-2:

FDA-recognized, voluntary consensus standards	
	General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ISO 15004-1:2020	Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
ISO 10940:2009	Ophthalmic instruments – Fundus cameras
ANSI Z80.36-2021	American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
IEC 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC62366-1:2015+AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60825-1: 2007	Safety of laser products - Part 1: Equipment classification, and requirements
ISO 10993-1:2018	Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
IEC 62304:2015	Medical device software - Software life cycle processes
NEMA PS 3.1 - 3.20 2021e	Digital Imaging and Communications in Medicine (DICOM) Set

Software for Maestro2 was concluded to be a Basic documentation level. Software verification and validation testing such as software system testing was performed for Maestreo2 as recommended by FDA's Guidance document *Content of Premarket Submissions for Device Software Functions (issued on June 14, 2023)*.

For the modified remote operation function, comparison testing confirmed that image quality and diagnosability is the same with or without the remote operation function.

Maestro2 is a cyber device per 524B(c) of the Food, Drug & Cosmetic Act. Maestro2 followed the recommendations in the FDA's Guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (issued on

September 27, 2023).

Clinical Performance Data

This section is not applicable because clinical data was not required for this 510(k) submission.

Substantial Equivalence

The subject device is substantially equivalent to the predicate device because the intended use/indications for use, operation principle and technological characteristics of the subject device is substantially equivalent to those of the predicate device as shown in **Table 1** below.

TABLE 1: SUBSTANTIAL EQUIVALENCE: MAESTRO2

Model Number	Subject Device 3D OCT-1 Maestro2	Predicate Device 3D OCT-1 Maestro2	Substantial Equivalence Discussion
Trade Name	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)	N/A
510(k) submitter/holder	TOPCON Corporation	TOPCON Corporation	Same
510(k) Number	K233561	K231222	N/A
Product code	OBO, HKI	OBO, HKI	Same
Regulation No.	21 C.F.R. § 886.1570	21 C.F.R. § 886.1570	Same
Product class	II	II	Same
Indications for Use	The TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) is a noncontact, 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 Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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.	The TOPCON 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) is a noncontact, 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 Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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.	Same

<table>
<tr><th>Model Number</th><th>Subject Device
3D OCT-1 Maestro2</th><th>Predicate Device
3D OCT-1 Maestro2</th><th>Substantial Equivalence Discussion</th></tr>
<tr><td></td><td>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 Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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.</td><td>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 Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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.</td><td></td></tr>
<tr><td>Device Specifications</td><td>
<table>
<tr><th>Item</th><th colspan="2">Device Specification</th></tr>
<tr><td colspan="3">Observation & photographing of the fundus</td></tr>
<tr><td>Type of photography</td><td colspan="2">Color, Red-free (Note 1) & IR (Note 3)</td></tr>
<tr><td>Picture angle for observation/photography</td><td colspan="2">45° ±5% or less 30° or equivalent (digital zoom)</td></tr>
<tr><td>Operating distance</td><td colspan="2">34.8 ±0.1mm (when taking a picture of fundus)</td></tr>
<tr><td>Observable/ photographable diameter of pupil</td><td colspan="2">ϕ4.0mm or more: When small pupil diaphragm is NOT used.
ϕ3.3mm or more: When small pupil diaphragm is used.</td></tr>
<tr><td>Fundus image resolution (on fundus)</td><td>Optical Function Center: 60 lines/mm or more Middle (r/2): 40 lines/mm or more Periphery</td><td>With Camera Center: 50 lines/mm or more Middle (r/2): 40 lines/mm or</td></tr>
</table>
</td><td>
<table>
<tr><th>Item</th><th colspan="2">Device Specification</th></tr>
<tr><td colspan="3">Observation & photographing of the fundus</td></tr>
<tr><td>Type of photography</td><td colspan="2">Color, Red-free (Note 1) & IR (Note 3)</td></tr>
<tr><td>Picture angle for observation/photography</td><td colspan="2">45° ±5% or less 30° or equivalent (digital zoom)</td></tr>
<tr><td>Operating distance</td><td colspan="2">34.8 ±0.1mm (when taking a picture of fundus)</td></tr>
<tr><td>Observable/ photographable diameter of pupil</td><td colspan="2">ϕ4.0mm or more: When small pupil diaphragm is NOT used.
ϕ3.3mm or more: When small pupil diaphragm is used.</td></tr>
<tr><td>Fundus image resolution (on fundus)</td><td>Optical Function Center: 60 lines/mm or more Middle (r/2): 40 lines/mm or more</td><td>With Camera Center: 50 lines/mm or more Middle (r/2): 40 lines/mm or</td></tr>
</table>
</td><td>Same</td></tr>
</table>

Model Number	Subject Device 3D OCT-1 Maestro2			Predicate Device 3D OCT-1 Maestro2			Substantial Equivalence Discussion
		(r): 25 lines/mm or more	more Periphery (r): 25 lines/mm or more		Periphery (r): 25 lines/mm or more	more Periphery (r): 25 lines/mm or more	
		IR photography: Center: 5 lines/mm or more (Note 3)			IR photography: Center: 5 lines/mm or more (Note 3)		
	Observation & photographing of the fundus tomogram			**Observation & photographing of the fundus tomogram**			
	Scan range (on fundus)	Horizontal direction 3 – 12mm ±5% or less Vertical direction 3 – 9mm ±5% or less		Scan range (on fundus)	Horizontal direction 3 – 12mm ±5% or less Vertical direction 3 – 9mm ±5% or less		
	Scan pattern	3D scan (horizontal) Linear scan (Line-scan/Cross-scan)		Scan pattern	3D scan (horizontal) Linear scan (Line-scan/Cross-scan)		
	Scan speed	50,000 A-Scans per second		Scan speed	50,000 A-Scans per second		
	Lateral resolution	20μm		Lateral resolution	20μm		
	In-depth resolution	6μm		In-depth resolution	6μm		
	Photographable diameter of pupil	ϕ2.5mm or more		Photographable diameter of pupil	ϕ2.5mm or more		
	Observation & photographing of the fundus image/fundus tomogram			**Observation & photographing of the fundus image/fundus tomogram**			
	Fixation target	Internal fixation target: Dot matrix type organic EL display The display position can be changed and adjusted. The displaying method can be changed.		Fixation target	Internal fixation target: Dot matrix type organic EL display The display position can be changed and adjusted. The displaying method can be changed.		

Model Number	Subject Device 3D OCT-1 Maestro2	Predicate Device 3D OCT-1 Maestro2	Substantial Equivalence Discussion
	Peripheral fixation target: This is displayed according to the internal fixation target displayed position. External fixation target	Peripheral fixation target: This is displayed according to the internal fixation target displayed position. External fixation target	
	Observation & photographing of anterior segment	**Observation & photographing of anterior segment**	
	Type of photography: Color & IR (Note 3)	Type of photography: Color & IR (Note 3)	
	Operating distance: 62.6 ±0.1mm (when taking a picture of anterior segment) (Note 2)	Operating distance: 62.6 ±0.1mm (when taking a picture of anterior segment) (Note 2)	
	Observation & photographing of the anterior segment tomogram	**Observation & photographing of the anterior segment tomogram**	
	Operating distance: 62.6 ±0.1mm (when taking a picture of anterior segment) (Note 2)	Operating distance: 62.6 ±0.1mm (when taking a picture of anterior segment) (Note 2)	
	Scan range (on cornea) (Note 2): Horizontal direction 3 – 6mm ±5% or less Vertical direction 3 – 6mm ±5% or les	Scan range (on cornea) (Note 2): Horizontal direction 3 – 6mm ±5% or less Vertical direction 3 – 6mm ±5% or les	
	Scan pattern: Linear scan (Line-scan/Radial-scan)	Scan pattern: Linear scan (Line-scan/Radial-scan)	
	Scan speed: 50,000 A-Scans per second	Scan speed: 50,000 A-Scans per second	
	Fixation target: External fixation target	Fixation target: External fixation target	
Linkage with IMAGEnet6 via PC software for System Linkage	Yes	No	**Different** The difference in instrument and PC software does not affect the SE discussion because the programing language and core algorithm of the Maestro2 predicate and Maestro2 is the same.

Model Number	Subject Device 3D OCT-1 Maestro2	Predicate Device 3D OCT-1 Maestro2	Substantial Equivalence Discussion
Optional Remote operation function	Yes	No	**Different** For the modified remote operation function, comparison testing confirmed that image quality and diagnosability is the same with or without the remote operation function.

Conclusions

Topcon's 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2) is as safe and effective as the previously cleared 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2), K231222.