July 17, 2024

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

Re: K241081
Trade/Device Name: 3D OPTICAL COHERENCE TOMOGRAPHY (3D OCT-1(type: Maestro2)); IMAGEnet6 Ophthalmic Data System
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HKI, NFJ
Dated: April 18, 2024
Received: April 19, 2024

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241081

Device Name
• 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)
• IMAGEnet6 Ophthalmic Data System

Indications for Use *(Describe)*

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

The Topcon 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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.

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 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.

It 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.

All the above functionalities and indications are available in combination with IMAGEnet 6.

• Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6

Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye including the retina, optic disc and choroid.

• IMAGEnet6 Ophthalmic Data System

The IMAGEnet6 Ophthalmic Data System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices.

It is intended for processing and displaying ophthalmic images and optical coherence tomography data.

The IMAGEnet6 Ophthalmic Data System uses the same algorithms and reference databases from the original data capture device as a quantitative tool for the comparison of posterior ocular measurements to a database of known normal subjects.

• Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6

Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye including the retina, optic disc and choroid.

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

I. 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:
July 16, 2024

II. Subject device:

Name of Device:	1) 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2) 2) IMAGEnet6 Ophthalmic Data System
Device Class:	Class II
Classification Name:	21 C.F.R. § 886.1570, Ophthalmoscope
Product Code:	OBO
Associated Product Code:	HKI, NFJ

III. Predicate devices:

PRIMARY PREDICATE DEVICE:

Company	Carl Zeiss Meditec, Inc.
Device	CIRRUS HD-OCT with Software Version 10
510(k) No.	K181534
Classification Name:	21 CFR § 886.1570 Ophthalmoscope
Product Code:	OBO

SECONDARY PREDICATE DEVICES:

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

Company	Topcon Corporation
Device	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)
510(k) No.	K233561
Classification Name:	21CFR § 886.1570 Ophthalmoscope
Product Code:	OBO, HKI

(2) IMAGEnet6 Ophthalmic Data System:

Company	Topcon Corporation
Device	IMAGEnet6 Ophthalmic Data System
510(k) No.	K232828
Classification Name:	21 C.F.R. § 892.2050 Medical image management and processing system
Product Code:	NFJ

IV. Brief Device Descriptions

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. 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. Maestro2 is capable of OCT imaging and color fundus photography. For this 510(k) notification, Maestro2 has been modified to allow for OCT "angiographic" imaging (only in conjunction with IMAGEnet6).

The software version for this 510(k) are:
Maestro2 Main software: Ver.3.00
PC Software for System Linkage: Ver.3.00

IMAGEnet6 Ophthalmic Data System

IMAGEnet6 is a software program installed on a server computer and operated via web browser on a client computer. It is used in acquiring, storing, managing, processing, measuring, displaying of patient information, examination information and image information delivered from TOPCON devices.

When combined with Maestro2, IMAGEnet6 plays an essential role as the user interface of the external PC by working together with the linkage software of Maestro2. In this configuration, IMAGEnet6 performs general GUI functions such as providing of the log-in screen, display of the menu icons, display function, measurement, analysis function, image editing functions, storing and management of data of the captured OCT scans and provides the reference database for quantitative comparison. For this 510(k) notification, IMAGEnet6 has been modified to allow for OCT "angiographic" imaging on the Maestro2.

IMAGEnet6 also provides the GUI for remote operation. This function is an optional function which enables end-users to use some of the image capture function by operating the PC or tablet PC connected to the external PC of Maestro2 via ethernet cable. 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.

The software version for this 510(k) is:
IMAGEnet6 Ophthalmic Data System Ver. 4.01

V. Intended use

The Maestro2 has the same intended use as the primary predicate and IMAGEnet 6 has the same intended use as the secondary predicate K232828. The modified Maestro2 and IMAGEnet6 devices will have the following Indications for Use (IFU) statements, which are not substantially different from those of the primary and/or secondary predicates:

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 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.

  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 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.

It 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.

All the above functionalities and indications are available in combination with IMAGEnet 6.

- **IMAGEnet6 Ophthalmic Data System**

  The IMAGEnet6 Ophthalmic Data System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices.

  It is intended for processing and displaying ophthalmic images and optical coherence tomography data.

  The IMAGEnet6 Ophthalmic Data System uses the same algorithms and reference databases from the original data capture device as a quantitative tool for the comparison of posterior ocular measurements to a database of known normal subjects.

- **Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6**

  Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye including the retina, optic disc and choroid.

VI. Comparison of the technological characteristics between the subject and predicate devices

The subject and predicate devices do not share identical technological characteristics. However, these differences do not raise new or different questions of safety and effectiveness.

Comparison of the technological characteristics between the subject and predicate devices are summarized in Tables 1, 2 and 3 below.

TABLE 1: PREDICATE COMPARISON–MAESTRO2 AND IMAGENET6 VERSUS PRIMARY PREDICATE ON OCT ANGIOGRAPHY

(Under lines shows the differences.)

Model Number	**Subject Device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.3.00 PC Software for System Linkage: Ver.3.00	**Subject Device IMAGEnet6** Software version Ver4.01	**Primary predicate device CIRRUS HD-OCT**	**Substantial Equivalence Discussion**
Trade Name	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)	Ophthalmic Data System IMAGEnet6	CIRRUS HD-OCT	NA
510(k) submitter	TOPCON Corporation	TOPCON Corporation	Carl Zeiss Meditec, Inc.	NA
510(k) Number	K241081	K241081	K181534	NA
Primary Product code	OBO	OBO	OBO	Same
Regulation No.	21 C.F.R. § 886.1570	21 C.F.R. § 886.1570* *Due to bundling of Maestro2 and IMAGEnet6 under the same 510(k) submission	21 C.F.R. § 886.1570	Same
Product class	II	II	II	Same
Indications for Use	The Topcon 3D Optical Coherence Tomography 3D OCT-1 (Type:Maestro2) 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. 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 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	The IMAGEnet6 Ophthalmic Data System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices. It is intended for processing and displaying ophthalmic images and optical coherence tomography data. The IMAGEnet6 Ophthalmic Data System uses the same algorithms and reference databases from the original data capture device as a quantitative tool for the comparison of posterior ocular measurements to a database of known normal subjects.	CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures. The device is indicated for visualizing and measuring anterior and posterior ocular structures, including cornea, corneal epithelium, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The CIRRUS normative databases are quantitative tools indicated for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of normal subjects. CIRRUS' AngioPlex OCT	Similar. The combination of Maestro2 and IMAGEnet6 is similar to the CIRRUS HD-OCT. Both are OCT imaging systems with a reference database (RDB), OCTA and fundus camera features. Clinical performance testing was conducted on the OCTA function of Maestro2 (and IMAGEnet6 combination) and on the CIRRUS HD-OCT.

(Under lines shows the differences.)				
Model Number	**Subject Device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.3.00 PC Software for System Linkage: Ver.3.00	**Subject Device IMAGEnet6** Software version Ver4.01	**Primary predicate device CIRRUS HD-OCT**	**Substantial Equivalence Discussion**
	to a database of known normal subjects. It 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. All the above functionalities and indications are available in combination with IMAGEnet 6.		Angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid. (Model 5000 only.) CIRRUS HD-OCT is indicated as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.	
Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6	Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye including the retina, optic disc and choroid.		NA	
Light Source	Spectral domain OCT (SDOCT) using a super luminescent diode (SLD) with center wavelength 840 nm.	NA	Spectral domain OCT (SDOCT) using a super luminescent diode (SLD) with center wavelength 840 nm.	Same
Scan Speed	50,000 A-scans/sec	NA	27,000 A-scans/sec 68,000 A-scans/sec for OCT Angiography	**Different.** There is a difference in scan speed. Clinical performance testing was conducted on the OCTA function of Maestro2 and IMAGEnet6 combination and on the CIRRUS HD-OCT.
A-scan Depth	2.6 mm (in tissue)	NA	2.0 mm	**Different.** Clinical performance testing was conducted on the OCTA function of Maestro2 and IMAGEnet6 combination and

(Under lines shows the differences.)				
Model Number	**Subject Device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.3.00 PC Software for System Linkage: Ver.3.00	**Subject Device IMAGEnet6** Software version Ver4.01	**Primary predicate device CIRRUS HD-OCT**	**Substantial Equivalence Discussion**
				on the CIRRUS HD-OCT.
Resolution	Axial: 6 μm (in tissue) Transverse: 20 μm (in tissue)	NA	Axial: 5 μm (in tissue) Transverse: ≤15 μm	**Different.** Clinical performance testing was conducted on the OCTA function of Maestro2 and IMAGEnet6 combination and on the CIRRUS HD-OCT.
Scan Patterns	For posterior 3D scan - 12x9 mm (512x128) - 6x6 mm (512x128) Line scan - 6 mm (1024) - 9 mm (1024) 5LineCross scan - 6 mm (1024) x 5 x 2 - 9 mm (1024) x 5 x 2 For anterior Radial scan - 6 mm x 12 (1024x12) Line scan - 3 mm (1024) - 6 mm (1024)	NA	Macular Cube - 6x6 mm (512x128) - 6x6 mm (200x200) Optic Disc Cube - 6x6 mm (200x200) 5 Line Raster HD (high-definition) Raster - HD 1 Line 100x - HD 21 Line - HD Radial - HD Cross - HD 5-Line Raster Anterior Segment Cube Scan 512x128 Anterior Segment 5-Line Raster HD Angle Anterior Chamber Wide-to-Angle HD Cornea Pachymetry	Similar
OCTA Scan Patterns	Macular - 3x3mm (256x256) - 6x6mm (360x360) Disc: - 4.5x4.5mm (320x320)	NA	AngioPlex - 3x3 mm - 6x6 mm - 8 x8 mm	Different. Clinical performance testing was conducted on the OCTA function of Maestro2 and IMAGEnet6 combination and on the CIRRUS HD-OCT.
OCTA algorithm	OCTARA	NA	OMAG	**Different** Clinical performance

(Under lines shows the differences.)				
Model Number	**Subject Device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.3.00 PC Software for System Linkage: Ver.3.00	**Subject Device IMAGEnet6** Software version Ver4.01	**Primary predicate device CIRRUS HD-OCT**	**Substantial Equivalence Discussion**
				testing was conducted on the OCTA function of Maestro2 and IMAGEnet6 combination and on the CIRRUS HD-OCT.
Default OCTA en face slabs	NA	Macular scans default slabs Superficial- ILM to IPL/INL + 15.6µm Deep- IPL/INL + 15.6µm to IPL/INL + 70.2µm Outer Retina- IPL/INL + 70.2µm to BM Choriocapillaris- BM to BM + 20.8µm Disc scans default slabs Vitreous- Top to ILM Optic Disc- ILM to BM – 50µm RPC- ILM to RNFL/GCL Choriocapillaris- BM to BM + 20.8µm	Macular scans default slabs Superficial- ILM to IPL Deep- IPL to OPL Avascular- OPL to RPE – 70µm Choriocapillaris- RPE + 29µm to RPE + 49µm Disc scans default slabs Vitreous Retinal Interface- ILM – 300µm to ILM Retina- ILM to RPE RPC- ILM to RNFL	**Different** Clinical performance testing was conducted on the OCTA function of Maestro2 and IMAGEnet6 combination and on the CIRRUS HD-OCT.
Layer Segmentation	**For posterior:** 1. ILM 2. RNFL/GCL 3. IPL/INL 4. OS/RPE 5. BM **For anterior:** N/A	Manual adjustment of segmented layer.	Unknown	Similar.
Quantitative Analyses	**For posterior:** - Retinal layer segmentation - Optic disc analysis **OCTA:** None (qualitative visualization only) **For anterior:** N/A	Thickness calculation	**For posterior:** • RNFL, Macula, Anterior Segmentation • RNFL Thickness analysis • Optic Nerve Head (ONH) analysis • Guided Progression Analysis (GPA) for RNFL • Guided Progression Analysis (GPA) for Ganglion Cell/IPL • Macular Thickness Analysis • Ganglion Cell OU Analysis • Advanced RPE Analysis • PanoMap Analysis **For anterior:**	Similar. There are no quantitative analyses associated with OCTA imaging from either the Maestro2 or CIRRUS HD-OCT.

(Under lines shows the differences.)				
Model Number	**Subject Device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.3.00 PC Software for System Linkage: Ver.3.00	**Subject Device IMAGEnet6** Software version Ver4.01	**Primary predicate device CIRRUS HD-OCT**	**Substantial Equivalence Discussion**
			• Anterior Segment-Analysis with quantitative measurement tools.	
Display of En-face images	NA	YES	YES	Same
Fundus imaging available	Yes	NA	Yes	Same

TABLE 2 SUBSTANTIAL EQUIVALENCE - MAESTRO2 VERSUS SECONDARY PREDICATE DEVICE

(Under lines shows the differences.)			
Model Number	**Subject Device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.3.00 PC Software for System Linkage: Ver.3.00	**Secondary predicate device 3D OCT-1 Maestro2** Software version Maestro2 Main software: Ver.2.11.1 PC Software for System Linkage: Ver.2.11.1	**Substantial Equivalence Discussion**
Trade Name	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)	3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1(type: Maestro2)	Same
510(k) submitter	TOPCON Corporation	TOPCON Corporation	Same
510(k) Number	K241081	K233561	NA
Primary Product code	OBO	OBO	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 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. 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 disc as	The 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	**Different.** The modified Maestro2 can perform OCT Angiography in combination with IMAGEnet6.

(Under lines shows the differences.)			
	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. It 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. All the above functionalities and indications are available in combination with IMAGEnet 6. Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6 Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye including the retina, optic disc and choroid.	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 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.	
Light Source	Spectral domain OCT (SDOCT) using a super luminescent diode (SLD) with center wavelength 840 nm.	Spectral domain OCT (SDOCT) using a super luminescent diode (SLD) with center wavelength 840 nm.	Same
Scan Speed	50,000 A-scans/sec	50,000 A-scans/sec	Same
A-scan Depth	2.6 mm (in tissue)	2.6 mm (in tissue)	Same
Resolution	Axial: 6 micron (in tissue) Transverse: 20 micron (in tissue)	Axial: 6 micron (in tissue) Transverse: 20 micron (in tissue)	Same
Scan Patterns	**For posterior:** **3D scan** - 12x9 mm (512x128) - 6x6 mm (512x128) **Line scan** - 6mm (1024) - 9mm (1024) **5LineCross scan** - 6mm (1024) x 5 x 2 - 9mm (1024) x 5 x 2 **For anterior:** **Radial scan** - 6mm x 12 (1024x12) **Line scan** - 3mm (1024) - 6mm (1024)	**For posterior:** **3D scan** - 12x9 mm (512x128) - 6x6 mm (512x128) **Line scan** - 6mm (1024) - 9mm (1024) **5LineCross scan** - 6mm (1024) x 5 x 2 - 9mm (1024) x 5 x 2 **For anterior:** **Radial scan** - 6mm x 12 (1024x12) **Line scan** - 3mm (1024) - 6mm (1024)	Same
Layer Segmentation	**For posterior:** 1. ILM 2. RNFL/GCL 3. IPL/INL 4. OS/RPE 5. Bruch's membrane (BM)	**For posterior:** 1. ILM 2. RNFL/GCL 3. IPL/INL 4. OS/RPE	Different. To support the addition of OCTA imaging, the Maestro2 was modified to be able to detect

(Under lines shows the differences.)			
	For anterior: N/A	**For anterior:** N/A	BM.
Thickness Calculation	No	No	Same
Analysis	Yes	Yes	Same
OCTA image capture	Macular - 3x3mm (256x256) - 6x6mm (360x360) Disc: - 4.5x4.5mm (320x320)	None	**Different.** Addition of OCTA-specific scan patterns for acquisition of OCTA images.
Image	Color/Digital red-free image	Color/Digital red-free image	Same
Angle of View	45 degree 30 degree (digital zoom)	45 degree 30 degree (digital zoom)	Same
Operating Distance	34.8 mm (fundus photography) 62.6 mm (anterior photography)	34.8 mm (fundus photography) 62.6 mm (anterior photography)	Same
Dioptric Compensation	-33D to +40D	-33D to +40D	Same
Power Source	Voltage/frequency: AC 100-240V/50-60Hz Power input: 70-150VA	Voltage/frequency: AC 100-240V/50-60Hz Power input: 70-150VA	Same
Overall Dimensions	340-480mm (W) × 543-680mm (D) × 500 -735mm(H)	340-480mm (W) × 543-680mm (D) × 500 -735mm(H)	Same
Linkage with IMAGEnet6 via PC software for System Linkage	Yes	Yes	Same
Optional Remote operation function	Yes	Yes	Same

TABLE 3 SUBSTANTIAL EQUIVALENCE – IMAGENET6 VERSUS SECONDARY PREDICATE DEVICE ON FUNCTION OTHER THAN OCT ANGIOGRAPHY

(Under lines shows the differences.)			
Model Number	**Subject Device** **IMAGEnet6** Software version Ver4.01	**Secondary predicate device** **IMAGEnet6 predicate** Software version Ver2.52.1	**Substantial Equivalence Discussion**
Trade Name	Ophthalmic Data System IMAGEnet6	Ophthalmic Data System IMAGEnet6	N/A
510(k) submitter	TOPCON Corporation	TOPCON Corporation	Same
510(k) Number	K241081	K232828	N/A
Primary Product code	OBO	NFJ	Different. This difference is due to the bundling rule and does not affect SE.
Regulation No.	21 C.F.R. § 886.1570	21 CFR 892.2050	Different. This difference is due to the bundling rule and does not

(Under lines shows the differences.)			
			affect SE.
Product class	II	II	Same
Indications for use	The IMAGEnet6 Ophthalmic Data System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices. It is intended for processing and displaying ophthalmic images and optical coherence tomography data. The IMAGEnet6 Ophthalmic Data System uses the same algorithms and reference databases from the original data capture device as a quantitative tool for the comparison of posterior ocular measurements to a database of known normal subjects. Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6 Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of vascular structures of the posterior segment of the eye including the retina, optic disc and choroid.	The IMAGEnet6 Ophthalmic Data System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices. It is intended for processing and displaying ophthalmic images and optical coherence tomography data. The IMAGEnet6 Ophthalmic Data System uses the same algorithms and reference databases from the original data capture device as a quantitative tool for the comparison of posterior ocular measurements to a database of known normal subjects.	**Different.** The modified Maestro2 can perform OCT Angiography in combination with IMAGEnet6
Connectable devices	TRC-50DX TRC-NW300 TRC-NW7SF MARK III TRC-NW8 TRC-NW8F TRC-NW8F plus TRC-NW400 DC-3 DC-4 3D OCT-1000 3D OCT-2000 3D OCT-1 Maestro 3D OCT-1(Type: Maestro2) DRI OCT Triton CA-800 KR-800PA Aladdin NW500	TRC-50DX TRC-NW300 TRC-NW7SF MARK III TRC-NW8 TRC-NW8F TRC-NW8F plus TRC-NW400 DC-3 DC-4 3D OCT-1000 3D OCT-2000 3D OCT-1 Maestro 3D OCT-1(Type: Maestro2) DRI OCT Triton CA-800 KR-800PA Aladdin NW500	Same
Database	YES	YES	Same
Patient management	YES	YES	Same
Acquisition	YES	YES	Same
Archive and Backup	YES	YES	Same
DVD / CD-R for archiving	YES	YES	Same

(Under lines shows the differences.)			
Image processing	YES	YES	Same
Import/Export images DICOM	YES	YES	Same
Combination with Maestro2	YES	YES	Same
Display OCTA data and creation of En-face image	YES	None	**Different** Addition of OCTA data. This function is evaluated with the primary predicate device.

VII. Non-clinical performance testing

It has been verified that Maestro2 and IMAGEnet6 functions as intended by tests or evaluations based on the following FDA-recognized, voluntary consensus standards, and the in-house test specification. The result of the testing supports substantial equivalence by demonstrating that the device(s) perform as intended and comply with the same standards as the predicate device(s).

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

FDA-recognized, voluntary consensus standards	
IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
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: 2020	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

FDA-recognized, voluntary consensus standards	
ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
IEC 62304:2015	Medical device software - Software life cycle processes
ISO 14155: 2020	Clinical investigation of medical devices for human subjects - Good clinical practice

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

For the remote operation function cleared in K233561, 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).

IMAGEnet6 Ophthalmic Data System

FDA-recognized, voluntary consensus standards	
IEC 62304:2015	Medical device software - Software life cycle processes
NEMA PS 3.1 - 3.20 2022d	Digital Imaging and Communications in Medicine (DICOM) Set
ISO 14155: 2020	Clinical investigation of medical devices for human subjects - Good clinical practice

Software for IMAGEnet6 was concluded to be a Basic Documentation Level. Software verification and validation testing such as software system testing was performed for IMAGEnet6 as recommended by FDA's Guidance document *Content of Premarket Submissions for Device Software Functions (issued on June 14, 2023)*.

For the remote operation function cleared in K232828, comparison testing confirmed that image quality and diagnosability is the same with or without the remote operation function.

IMAGEnet6 is a cyber device per 524B(c) of the Food, Drug & Cosmetic Act. IMAGEnet6 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).

VIII. Clinical performance testing

A prospective, multi-center, observational study was conducted to compare the OCTA imaging performance (i.e., image quality and visualization of vascular features in the macula and optic disc) of the Maestro2 and the CIRRUS HD-OCT and to compare visualization of pathologic vascular features in the retina and choroid between the Maestro2 and CIRRUS HD-OCT versus dye-based angiography (e.g., fluorescein angiography). Maestro2 and CIRRUS HD-OCT images (OCTA macula 3x3-mm scan, macula 6x6-mm scan, and disc 4.5x4.5-mm scan) collected by the clinical sites were sent to an independent reading center (RC) for image grading. Participants age 22 years or older with or without relevant vascular pathology in at least one eye were enrolled and assigned to one of two groups: 1) "Normal Population" ("eyes without clinically significant pathology") and 2) "Pathology Population" ("eyes with vascular pathologies affecting different anatomical depths of the retina and choroid"). Best-corrected visual acuity (BCVA, in the study eye) in the "Pathology Population" was required to be 20/400 or better, in the "Normal Population 20/40 or better. The "Pathology Population" group was further stratified by vascular pathology primarily in the Outer Retina and/or Choriocapillaris slabs vs. vascular pathology in the Superficial and/or Deep slabs. The following endpoints were evaluated:

1. OCTA image "quality response rate" (percentage of eyes whose Maestro2 scans have the same or better grade than the corresponding CIRRUS HD-OCT scans).

2. Visibility of key anatomical vascular features (foveal avascular zone [FAZ] border, large blood vessels, medium blood vessels, and small blood vessels/capillaries) "response rate" (percentage of eyes whose Maestro2 scans have the same or better grade than the corresponding CIRRUS HD-OCT scans).

3. Positive percent agreement (PPA) and negative percent agreement (NPA) between Maestro2 and CIRRUS HD-OCT in the identification of key pathological vascular features (microaneurysms [MA], retinal ischemia/capillary dropout [RI/CD], and choroidal neovascularization [CNV]). In addition, a "response rate" was calculated based on the match outcome based on whether pathology identification was the same (i.e., a "match") between OCTA and FA/ICGA (percentage of eyes whose Maestro2 scans have the same or better outcome than the corresponding CIRRUS HD-OCT scans).

133 participants were enrolled. There were 41 eyes in the "normal" group, 93 eyes in the "pathology" group. 124 eyes of 122 subjects fulfilled eligibility criteria. Primary analyses were based on a cohort of these 124 eyes (eligible eyes with OCTA or FA/ICGA imaging; 38 "normal," 86 "pathology"). Participant age ranged from 22 to 87 years, with a mean age of 54.1±18.4 years (37.9 years in the "normal" group, 61 years in the "pathology" group). 45.9% (56/122) were men and 54.1% (66/122) were women. 71.3% (87/122) are White, 17.2% (21/122) Black/African American, 1.6% (2/122) American Indian/Alaskan Native, 7.4% (9/122) Asian, 0.8% (1/122) Native Hawaiian/Pacific Islander, and 2.5% (3/122)

Other. 18.0% (22/122) are Hispanic or Latino and 82.0% (100/122) are not. In the "pathology" sub-group, 25.6% (22/86) had neovascular age-related macular degeneration, 22.1% (19/86) had non-proliferative diabetic retinopathy, 11.6% (10/86) had "other" retinal conditions (e.g., choroidal rupture), 10.5% (9/86) had proliferative diabetic retinopathy, 10.5% had branch retinal vein occlusion, 9.3% (8/86) had polypoidal choroidal vasculopathy, 8.1% had myopic CNV, 5.8% (5/86) had central retinal vein occlusion, 4.7% (4/86) had macular telangiectasia, 2.3% (2/86) had sickle cell retinopathy, 2.3% had central serous chorioretinopathy with CNV, and 2.3% had traumatic CNV. The distribution of vascular abnormalities is shown in the following table:

TABLE 4: ABNORMALITY OF STUDY EYES PER PRINCIPAL INVESTIGATOR (ANALYSIS POPULATION)

Retinal Abnormality[1]	Normal N = 38 n (%)	Pathology N = 86 n (%)	Total N = 124 n (%)
Abnormalities			
None	38 (100%)	0 (0.0%)	38 (30.6%)
Retinal Ischemia (capillary dropout) (RI/CD)	0 (0.0%)	11 (12.8%)	11 (8.9%)
Microaneurysm (MA)	0 (0.0%)	29 (33.7%)	29 (23.4%)
Macroaneurysms	0 (0.0%)	0 (0.0%)	0 (0.0%)
Choroidal neovascularization (CNV)	0 (0.0%)	28 (32.6%)	28 (22.6%)
Retinal neovascularization (RNV)	0 (0.0%)	11 (12.8%)	11 (8.9%)
Macular Telangiectasia (MacTel)	0 (0.0%)	4 (4.7%)	4 (3.2%)
Sickle Cell Retinopathy	0 (0.0%)	2 (2.3%)	2 (1.6%)
Polypoidal choroidal vasculopathy (PCV)	0 (0.0%)	7 (8.1%)	7 (5.6%)
Intraretinal microvascular abnormalities (IRMA)	0 (0.0%)	4 (4.7%)	4 (3.2%)
Retinal Tortuosity	0 (0.0%)	9 (10.5%)	9 (7.3%)
Geographic Atrophy	0 (0.0%)	4 (4.7%)	4 (3.2%)
Branch Retinal Vein Occlusion (BRVO)	0 (0.0%)	7 (8.1%)	7 (5.6%)
Central Retinal Vein Occlusion (CRVO)	0 (0.0%)	5 (5.8%)	5 (4.0%)
Central Retinal Arterial Occlusion (CRAO)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	19 (22.1%)	19 (15.3%)
Primary Pathology of Interest (PPOI)			
None	38 (100%)	--	38 (30.6%)
Retinal Ischemia (capillary dropout) (RI/CD)	--	6 (7.0%)	6 (4.8%)
Microaneurysm (MA)	--	15 (17.4%)	15 (12.1%)
Macroaneurysms	--	1 (1.2%)	1 (0.8%)
Choroidal neovascularization (CNV)	--	21 (24.4%)	21 (16.9%)
Retinal neovascularization (RNV)	--	6 (7.0%)	6 (4.8%)
Macular Telangiectasia (MacTel)	--	4 (4.7%)	4 (3.2%)
Sickle Cell Retinopathy	--	2 (2.3%)	2 (1.6%)
Polypoidal choroidal vasculopathy (PCV)	--	8 (9.3%)	8 (6.5%)
Intraretinal microvascular abnormalities (IRMA)	--	2 (2.3%)	2 (1.6%)
Retinal Tortuosity	--	5 (5.8%)	5 (4.0%)
Geographic Atrophy	--	1 (1.2%)	1 (0.8%)
Branch Retinal Vein Occlusion (BRVO)	--	4 (4.7%)	4 (3.2%)
Central Retinal Vein Occlusion (CRVO)	--	4 (4.7%)	4 (3.2%)

Other	--	7 (8.1%)	7 (5.6%)

[1] An eye could have multiple retinal conditions.

The following results were obtained for the above endpoints:

1. Results for the image quality response rate for the entire cohort were as follows: for the 3x3-mm macular scan, 6x6-mm macular scan, and 4.5x4.5-mm disc scan were 75.0%, 71.0% and 71.0%, respectively. The overall response rates for the "pathology" group between the two devices for the 3x3-mm macular scan, 6x6-mm macular scan, and 4.5x4.5-mm disc scan were 75.6%, 77.9% and 74.4%, respectively.

2. Results for visibility of key anatomical features for the entire cohort were as follows: for the 3x3-mm macular scan, the response rates for FAZ visibility, medium vessels, and small vessels/capillaries were 87.1%, 87.9%, and 82.3%, respectively. For the 6x 6-mm macular scan, the response rates for FAZ visibility, large vessels, medium vessels, and small vessels/capillaries were 81.5%, 87.1%, 77.4%, and 79.8%, respectively. For the 4.5x4.5-mm disc scan, the response rates for visibility of large vessels, medium vessels, and small vessels/capillaries were 83.9%, 80.6%, and 80.6%, respectively.

3. Results for key pathological vascular features for the "pathology" group were as follows:

    a. The Maestro2 PPA and NPA for microaneurysms (MAs) were 96.6% and 92.7% for 3×3-mm macular scans, respectively; 96.6% and 92.7% for 6×6-mm macular scans, respectively; 73.9% and 100% for 4.5×4.5-mm disc scans, respectively. The response rates for identification of MAs were 81.0% and 82.1% for the 3×3-mm and 6×6-mm macular scans, respectively. The MA response rate was 75.6% for the 4.5×4.5-mm disc scan.

    b. The Maestro2 PPA and NPA for RI/CD were 93.1% and 85.4% for 3×3-mm scans, respectively; 100% and 87.8% for 6×6-mm scans, respectively; 75.0% and 85.7% for 4.5×4.5-mm disc scans, respectively. The response rates were 76.2%, 79.8%, and 71.8% for the 3×3-mm macular, 6×6-mm macular, and 4.5×4.5-mm disc scans, respectively.

    c. The Maestro2 PPA and NPA for CNV were 88.9% and 82.7% for 3×3-mm macular scans, respectively; 84.2% and 84.3% for 6×6-mm macular scans, respectively; and 66.7% and 98.4% for 4.5×4.5-mm disc scans, respectively. The response rates were 79.8% and 81.0% for the 3×3-mm and 6×6-mm macular scans and 75.3% for the disc scan.

IX. Conclusions

The Maestro2 and the IMAGEnet6 have the same intended uses as the legally marketed

predicate devices identified in this 510(k) notification. The Indications for Use (IFU) statements differ from those of the predicate devices, but these differences do not change the intended use of the devices. The technological characteristics of the Maestro2 and IMAGEnet6 differ from those of the predicate devices, however, the differences do not raise new or different questions of safety or effectiveness. Results of the non-clinical performance testing demonstrate that Maestro2 and IMAGEnet6 function as intended. Results of the clinical performance testing demonstrate a favorable clinical performance profile that supports a determination of substantial equivalence.