March 01, 2024

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

Re: K232828
Trade/Device Name: IMAGEnet6 Ophthalmic Data System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: January 26, 2024
Received: January 26, 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 re11gulatory 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,

Alexander Beylin -S 2024.03.01 14:35:46 -05'00'

for Elvin Ng
Assistant Director
THT1A3: Retinal and Diagnostics Devices Team
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)*
K232828

Device Name
IMAGEnet6 Ophthalmic Data System

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY
TOPCON CORPORATION
Traditional 510(k) for:
IMAGEnet6 Ophthalmic Data System

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:
March 1, 2024

DEVICE INFORMATION

SUBJECT DEVICE:

IMAGEnet6 Ophthalmic Data System

Name of Device:	IMAGEnet6 Ophthalmic Data System
Device Class:	Class II
Classification Name:	21 C.F.R. § 892.2050 Medical image management and processing system
Product Code:	NFJ

PREDICATE DEVICE:

IMAGEnet6 Ophthalmic Data System:

Company	Topcon Corporation
Device	IMAGEnet6 Ophthalmic Data System
510(k) No.	K171370
Classification Name:	21 C.F.R. § 892.2050

	Medical image management and processing system
Product Code:	NFJ
Subsequent Product Codes	HKI, OBO

Brief Device Description

IMAGEnet6 Ophthalmic Data System
IMAGEnet6 Ophthalmic Data System is a Web application that allows management of patient information, exam information and image information. It is installed on a server PC and operated via a web browser of a client PC.

When combined with 3D OCT-1 (type: Maestro2), IMAGEnet6 provides GUI for remote operation function. This function is an optional function which enables users to use some of the image capture function by operating the PC or tablet PC connected to the external PC of 3D OCT-1 (Type:Maestro2) device 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.

Intended Use / Indications for Use

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.

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.

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

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 modified remote operation function, 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).

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: IMAGENET6

Model Number	**Subject Device IMAGEnet6 (ver2.52.1)**	**Predicate device IMAGEnet6 (ver1.52)**	**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	K232828	K171370	N/A
Product code	NFJ	NFJ	Same
Regulation No.	21 CFR 892.2050	21 CFR 892.2050	Same
Product class	II	II	Same
Intended purpose	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	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	**Different** Deleted the following sentence due to addition of remote operation

Model Number	Subject Device IMAGEnet6 (ver2.52.1)	Predicate device IMAGEnet6 (ver1.52)	Substantial Equivalence Discussion
	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.	and clinical information from TOPCON devices without controlling or altering the functions or parameters of any medical devices or through computerized networks. 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.	function: *without controlling or altering the functions or parameters of any medical devices or through computerized networks.* This difference does not affect the SE discussion because comparison testing confirmed that image quality and diagnosability is the same with or without the remote operation function.
Connectable devices	TRC-50DX, TRC-NW300, TRC-NW7SF MARK III TRC-NW8, TRC NW8F, TRC NW8F plus, TRC NW400, NW500 DC-3, DC-4 3D OCT-1000, 3D OCT-2000, 3D OCT-1 3D OCT-1(Type: Maestro2), DRI OCT Triton, CA-800, KR-800PA, Aladdin,	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	**Different** The following device connections have been added: 3D OCT-1(Type: Maestro2), DRI OCT Triton, CA-800, KR-800PA, Aladdin, NW500 This difference does not affect the SE discussion because the intended purpose to collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices does not change from the predicate device even connectable device is added.

Model Number	Subject Device IMAGEnet6 (ver2.52.1)	Predicate device IMAGEnet6 (ver1.52)	Substantial Equivalence Discussion
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
Image processing	YES	YES	Same
Import/Export images DICOM	YES	YES	Same
Interacts with OTS PC installed software of Maestro2	YES	NO	**Different** IMAGEnet6 now interacts with the OTS PC installed software of Maestro2. This difference does not affect the SE discussion because the intended purpose to collection, storage and management of digital images, patient data, diagnostic data and clinical information from Topcon devices does not change from the predicate device even connectable device is added. For the modified remote operation function, comparison testing confirmed that image quality and diagnosability is the same with or without the remote operation

Model Number	Subject Device IMAGEnet6 (ver2.52.1)	Predicate device IMAGEnet6 (ver1.52)	Substantial Equivalence Discussion
			function.

Conclusions

Topcon's IMAGEnet 6 Ophthalmic Data System (version 2.52.1) is as safe and effective as the previously cleared IMAGEnet 6 (version 1.52), K171370.