November 1, 2017

Topcon Corporation
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K171370
Trade/Device Name: IMAGEnet 6 Ophthalmic Data System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ, OBO, HKI
Dated: September 29, 2017
Received: October 2, 2017

Dear Maureen O'Connell:

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 (DICE) 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 (DICE) 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 yours,

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 below.

510(k) Number *(if known)*

K171370

Device Name
IMAGEnet 6 Ophthalmic Data System

Indications for Use *(Describe)*

The IMAGEnet 6 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 without controlling or altering the functions and parameters of any medical devices or through computerized networks. It is intended for processing and displaying ophthalmic images and optical coherence tomography data.

The IMAGEnet 6 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.

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
IMAGEnet 6 Ophthalmic Data System

510(k) Owner
Topcon Corporation
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, 174-8580
Japan
Phone: (201) 599-5187
Facsimile: (201) 599-5258
Contact Person: James Lorkowski, Regulatory Affairs Manager

Submission Correspondent:
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245

Date Prepared: October 26, 2017

Trade Name of Device
IMAGEnet 6 Ophthalmic Data System

Common or Usual Name
Picture archiving and communication system

Classification Name
System, image management, ophthalmic
21 C.F.R. 892.2050
Class II
Product Code: NFJ

Predicate Devices
Primary predicate: Topcon IMAGEnet 5 PC Software System (K132438)
Secondary predicates: Topcon 3D OCT-1 Maestro (K161509)

Device Description
IMAGEnet 6 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.

IMAGEnet 6 Ophthalmic Data System receives information from Topcon ophthalmological medical devices and saves the information including the patient information. The saved data can be displayed for diagnosis. In addition, it can save patient information, exam information, and image information as digital data to a database. These data can also be exported as digital data.

IMAGEnet 6 Ophthalmic Data System does not control or alter the functions or parameters of any medical device. IMAGEnet 6 Ophthalmic Data System is used in cooperation with the capture software designated for each capture device to retrieve image data such as an OCT image or a fundus image. IMAGEnet 6 Ophthalmic Data System receives, displays, and saves the image data captured with the capture software.

It also allows to send/receive patient information and image information, etc. to/from an external system via communication conforming to the DICOM standard.

Intended Use / Indications for Use

The IMAGEnet 6 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 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 IMAGEnet 6 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.

Substantial Equivalence

Topcon's IMAGEnet 5 cleared in K132438 is the primary predicate for the IMAGEnet 6 Ophthalmic Data System. In addition to the functionality which is substantially equivalent to the IMAGEnet 5, IMAGEnet 6 Ophthalmic Data System has the OCT viewer function which retrieves saved OCT data (both fundus and tomographic images) and views the OCT images in both 2D and 3D formats. In order to demonstrate substantial equivalence of these features, the software from the Topcon 3D OCT-1 Maestro (K161509) is the secondary predicate device for IMAGEnet 6 Ophthalmic Data System.

The IMAGEnet 6 Ophthalmic Data System and the primary predicate device are both ophthalmic picture archiving and communications systems that collect, store, and manage digital images of the eye. The vast majority of product features are the same in the IMAGEnet 6 Ophthalmic Data System as in the IMAGEnet 5 including database, patient management, retrieval, display and operation, measurement, image tools, archive and backup, networking and security, image processing, import/export of images, and DICOM compliance. One difference between the IMAGEnet 6 Ophthalmic Data System and the primary predicate is that the IMAGEnet 6 Ophthalmic Data System can manage exam data including visual acuity and intraocular pressure data. This feature is not available in the IMAGEnet 5, however, this minor difference does not impact the safety or effectiveness of the device.

The IMAGEnet 6 Ophthalmic Data System has an additional feature which is substantially equivalent to the software of the secondary predicate device. The secondary predicate device is the Topcon 3D OCT-1 Maestro device which was cleared in K161509. The IMAGEnet 6 Ophthalmic Data System uses the same algorithms and reference databases as the cleared device which allows comparison of posterior ocular measurements to a database of known normal subjects. Both IMAGEnet 6 Ophthalmic Data System and cleared Topcon 3D OCT-1 Maestro device have similar software related functionality including: display, analysis, and access to the reference database for OCT data.

Therefore, the minor differences between the subject device and the predicate devices do not raise new questions of safety or effectiveness. The Topcon IMAGEnet 6 is as safe and effective as its predicate devices, and thus, may be considered substantially equivalent.

Performance Data

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could lead to an erroneous diagnosis or delay in delivery of appropriate medical care that would likely lead to a minor injury.

Additionally, the IMAGEnet 6 Ophthalmic Data System was tested to demonstrate that the measurement and analysis functions are equivalent to the predicate devices and been found equivalent to the predicate devices.

Conclusions

Topcon's IMAGEnet 6 Ophthalmic Data System is as safe and effective as the previously cleared IMAGEnet 5 (K132438). In addition to the functionality which is substantially equivalent to the IMAGEnet 5, IMAGEnet 6 Ophthalmic Data System has the OCT viewer function which retrieves saved OCT data (both fundus and tomographic images) and views the OCT images in both 2D and 3D formats. In order to demonstrate substantial equivalence of these features, the software from the Topcon 3D OCT-1 Maestro (K161509) is a secondary predicate device for IMAGEnet 6. IMAGEnet 6 Ophthalmic Data System has the same intended use and similar indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices and is therefore substantially equivalent.