August 3, 2020

Topcon Healthcare Solutions, Inc.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K200954
Trade/Device Name: Glaucoma Module
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: June 24, 2020
Received: June 25, 2020

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200954

Device Name
Glaucoma Module

Indications for Use *(Describe)*
The Glaucoma Module is a software application intended for the management, display and analysis of visual field and optical coherence tomography data. It is intended as an aid to the detection and management of visual field defects and progression of visual field loss.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Topcon Healthcare Solutions
Glaucoma Module

510(k) Owner
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Date Prepared: July 30, 2020

Trade Name of Device
Glaucoma Module

Common or Usual Name
System, image management, ophthalmic

Classification Name
21 C.F.R. 892.2050
Picture Archiving and Communication System

Product Code
NFJ - System, Image Management, Ophthalmic

Predicate Device
Carl Zeiss Meditec AG's FORUM Glaucoma Workplace cleared in K141297

Intended Use / Indications for Use
The Glaucoma Module is a software application intended for the management, display and analysis of visual field and optical coherence tomography data. It is intended as an aid to the detection and management of visual field defects and progression of visual field loss.

Device Description
The Glaucoma Module works as an optional module, integrated into the Harmony user interface, and interfacing to Harmony to access the relevant data and information. Harmony is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye, as well as for management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic

instruments through either a direct connection with the instruments or through computerized networks. Harmony was most recently cleared by FDA in K182376.

The Glaucoma Module is a fully interactive multi-modality software for clinicians to assess, diagnose and manage patients who are glaucoma suspects or have been diagnosed with glaucoma. The Glaucoma Module is an aid to detection and management of visual field and OCT data.

The Glaucoma Module displays key information for diagnosis and management using a well-organized interface.

Glaucoma Module is integrated into the Harmony user interface that utilizes both OCT exam and Visual Field data in an interactive manner. It employs two main sections, the Hood Dashboard screen used to determine glaucoma suspects and the Glaucoma Trend screen which can be used to observe patient data over a larger period of time.

The Glaucoma Module does not include predictive interpretations of the correlation of structural and functional measures, two measures that are understood to be independent of each other.

The Glaucoma Module will work with the following medical devices:

- Topcon's Maestro, Maestro 2, and Triton Optical Coherence Tomography devices
- Zeiss' Visual Field instruments HFA3 and HFA Iii
- Visual Field data from other manufacturers, (e.g. Oculus EasyField) through DICOM OPV data format.

Performance Data
No performance data was required or provided. Software validation and verification demonstrate that the Glaucoma Module performs as intended and meets its' specifications.

Substantial Equivalence
The Glaucoma Module is substantially equivalent to Carl Zeiss Meditec AG's FORUM Glaucoma Workplace cleared in K141297**.** The Glaucoma Module has the same intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device**.** The intended use of the Glaucoma Module and the intended use of the FORUM Glaucoma Workplace cleared in K141297 are identical. Both systems are intended for use for the management, display and analysis of visual field and optical coherence tomography data.

The Glaucoma Module has the same technological characteristics as the FORUM Glaucoma Workplace (K141297). Both devices are software only image management systems which manage, display and analyze visual field and optical coherence tomography data. Both software devices access reference databases previously cleared by FDA. The Glaucoma Module accesses the Topcon's 3D OCT-1 Maestro (K170164) and Topcon's Triton (K173119) for RNFL thickness, ganglion cell plus inner plexiform thickness and optic nerve head measurements while the Zeiss FORUM Glaucoma Workplace references the Cirrus (K111157) algorithms and

normative database for RNFL thickness, ganglion cell plus inner plexiform thickness and optic nerve head measurements and the Humphrey Field Analyzer (K093213) for algorithms and databases for visual field measurements and Guided Progression Analysis.

Both the Glaucoma Module and the FORUM Glaucoma Workplace perform data retrieval from the allowed devices while the FORUM Glaucoma Workplace also allows for report storage. This minor difference between the devices does not impact substantial equivalence. Both devices manage, analyze and display OCT exams. The Glaucoma Module displays visual field reports and combined reports produced by the accessed devices while the FORUM Glaucoma Workplace also creates and combines visual field reports. As the Glaucoma Module is an optional add-on software this difference in reporting features does not impact substantial equivalence.

Both the Glaucoma Module and the FORUM Glaucoma Workplace display visual field information of a single exam while the FORUM Glaucoma Workplace also displays visual field information from multiple exams. Both software devices provide the same data plots: threshold, graytone, total deviation, pattern deviation and deviation from baseline. Both devices provide global indices for visual field progression and reliability indices and both allow comments to be added by the user. Neither device allows for storage of data.

In conclusion, the Glaucoma Module shares similar technological characteristics with the predicate device. As the Glaucoma Module is an optional add-on feature for the FDA cleared Harmony, the minor differences in features do not impact the substantial equivalence as both devices have the same core features and capabilities.

Conclusion

The Glaucoma Module has the same intended use as the previously cleared predicate device. In addition, the Glaucoma Module has similar technological characteristics as its predicate and is substantially equivalent to the predicate device.