November 20, 2023

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

Re: K232555
Trade/Device Name: Harmony
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: October 23, 2023
Received: October 23, 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)*
K232555

Device Name
Harmony

Indications for Use *(Describe)*
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 in 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.

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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K232555: Special 510(k) SUMMARY

Topcon Healthcare Solutions, Inc.
Harmony

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Date Prepared: November 16, 2023

Trade Name of Device
Harmony

Predicate Device
Topcon Harmony (K182376)

Classification Information

Regulation Number:	21 CFR 892.2050
Classification name:	Medical image management and processing system
Device Class:	Class II
Common name:	System, Image Management, Ophthalmic
Product Codes, Name:	NFJ

Intended Use / Indications for Use
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 in 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.

Device Description
Harmony is a modification to the existing Harmony cleared in K182376. The differences between the new version and the currently cleared version are modifications to the graphical user interface consisting of PixelSmart Technology, Internationalization support, Analytical thickness grids, Hanging protocols, and Automatic image smoothing while zooming in.

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 is used together with a number of computerized digital imaging devices, including:

- Optical Coherence Tomography devices
- Mydriatic retinal cameras
- Non-mydriatic retinal cameras
- Biomicroscopes (slit lamps)

In addition, Harmony collects and manages patient demographics, image data, and clinical reports from a range of medical devices, including:

- Scanning Laser Ophthalmoscope images and videos
- Non Radiometric Ultrasound devices
- Video image sources
- TWAIN compliant imaging sources
- Compliant data sources placed in network accessible folders and directories
- Images of known format from digital cameras and scanners
- Printer files of known format form computerized diagnostic devices
- Electronic information complying to accepted DICOM formats
- Other devices connected in proprietary formats

There are 5 notable device modifications subject of this submission: PixelSmart Technology, International support, Analytical thickness grids, Hanging protocols, and Automatic image smoothing while zooming in, along with some minor modifications.

PixelSmart is an optional post-processing image enhancement algorithm performing a moving average across OCT B-scans, reducing speckle noise and improving contrast by applying smoothing.

International support adds the possibility to use the Harmony user interface and online user manual in Spanish, in addition to the standard English software.

Analytical thickness grids offer the same functionality as the existing, cleared thickness grids in Topcon's IMAGEnet 6, now also in Harmony. The grids show sectorial average thickness values as derived from OCT segmentation data.

Hanging protocols allows a customizable image display arrangement in the Harmony user interface, resembling the arrangement of physical images on a light box.

Automatic image smoothing while zooming in is an optional display feature that will cause OCT B-scan images on higher zoom levels to look less pixelated.

Performance Data
Software validation and verification demonstrate that Harmony performs as intended and meets its specifications, using methods equivalent to the predicate device.

Substantial Equivalence
The modified Harmony is a device modification to the cleared Harmony (K182376) predicate device. Technological detail characteristics of the device are unchanged except for the modification as stated above. The modified Harmony has the same Indications for Use and maintains the same fundamental scientific technology as the predicate device.

The modified Harmony measures the same basic ophthalmic features as the cleared Harmony in K182376. The changes applied to the Harmony since the clearance in K182376 do not change the intended patient populations, the type of imported, displayed and analyzed images, or that the Harmony may be used as an aid to clinical workflows.

The basic functionality of the device is unchanged, which is a picture archiving and communication system (PACS). The device is still software only, which is unchanged by the modifications subject of this submission.

The modifications subject of this submission, PixelSmart Technology, Internationalization support, Analytical thickness grids, Hanging protocols, and Automatic image smoothing while zooming in, do not change the indications for use of the device, and do not change the manner in which images are imported, analyzed, and stored, or the operation of the device by the intended user.

Risk assessment was conducted on the modified Harmony as per existing design control, and the impact of the design modifications were assessed on the predicate 510(k) cleared device. Newly identified risks or modified existing risks are mitigated, and no unacceptable risk was identified remaining for the device after risk mitigation.

Topcon performed software validation and verification activities to confirm that the modified Harmony functions equivalently to the predicate Harmony.

Non-clinical performance testing was conducted on the modified Harmony to verify and validate that the device is safe and effective for its intended use and indications for use. The modified Harmony was evaluated according to the requirements of FDA recognized consensus standards:

- IEC 62304 Edition 1.1 2015-06: Medical Device Software - Software Life Cycle Processes
- NEMA PS 3.1 - 3.20 (2021), Digital Imaging And Communications In Medicine (DICOM) Set
- ISO IEC 10918-1 First edition 1994-02-15: Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including: Technical Corrigendum 1 (2005)]
- ISO 14971 Third Edition 2019-12: Medical devices - Application of risk management to medical devices

and was found to meet the requirements of the applicable parts, demonstrating that the safety and efficacy of the modified device is comparable to the predicate.

The modified Harmony is manufactured and tested in the exact manner as the predicate 510(k) cleared device.

The modifications to the device do not raise issues of safety and effectiveness. A comparison of technological characteristics and non-clinical performance testing demonstrate that the modified Harmony device is substantially equivalent to the unmodified predicate device.

Conclusion

Comparison of technological characteristics and evaluation of non-clinical performance testing show that the modifications to the Harmony do not introduce any new potential safety risk and the device is as safe and effective as the predicate devices, therefore supporting a determination of substantial

equivalence. Topcon's Harmony has the same intended use and indications for use as the previously cleared predicate device. In addition, Harmony has the same technological characteristics as its predicate. The modifications to the cleared version of Harmony are small and do not impact the substantial equivalence, thus the modified device is substantially equivalent to the predicate device.