September 13, 2021

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

Re: K210396
Trade/Device Name: Harmony Referral System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: August 18, 2021
Received: August 19, 2021

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)*

K210396

Device Name
Harmony Referral System (Harmony RS)

Indications for Use *(Describe)*

Harmony Referral System (Harmony RS) is a comprehensive software platform intended for use in importing, processing, viewing, measurement and storage of clinical images and videos as well as in management and communication of patient data, diagnostic and clinical information and reports from ophthalmic diagnostic instruments through either direct connection with the instruments or through computerized networks. The system neither performs any interpretations nor provides treatment recommendations.

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
Harmony Referral System (Harmony RS)

510(k) Owner
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Phone: (201) 599-5208
Contact Person: Ramya Sundaram

Submission Correspondent
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Date Prepared: August 16, 2021

Trade Name of Device
Harmony Referral System (Harmony RS)

Common or Usual Name
System, image management, ophthalmic

Classification Name
21 C.F.R. 892.2050
Medical Image Management and Processing System

Predicate Device
Topcon Harmony cleared in K182376

Indications for Use
Harmony Referral System (Harmony RS) is a comprehensive software platform intended for use in importing, processing, viewing, measurement and storage of clinical images and videos as well as in management and communication of patient data, diagnostic and clinical information and reports from ophthalmic diagnostic instruments through either direct connection with the instruments or through computerized networks. The system neither performs any interpretations nor provides treatment recommendations.

Device Description
Harmony Referral System is an internet-browser-based software platform that allows users to access examination data of a patient from different sources. Harmony Referral System may be used together with a number of computerized digital imaging devices and third party software. In

addition, Harmony Referral System software collects and manages patient demographics, image data, and clinical reports from a range of approved medical devices. Harmony Referral System enables a real-time review of diagnostic patient information at a PC workstation. The software uses SSL encryption in network communication and secure network infrastructure with firewalls and additionally also VPN and IP-based access restrictions to ensure secure networking environment. The Harmony Referral System does not perform automated image analysis but provides measurements based on pixels of an image, which were marked by the user manually on the screen including cup-disk ratio and line and area measurements.

Performance Data

No performance data was required or provided. Software validation and verification demonstrate that Harmony RS performs as intended and meets its' specifications.

Substantial Equivalence

The Harmony RS is substantially equivalent to Topcon Healthcare Solutions' Harmony cleared in K182376. The Harmony RS has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate. Both devices are software only image management systems which manage, display and analyze ophthalmic images.

Regarding acquisition, Harmony RS and Harmony (K182376) do not offer capture components. Both devices import digital images, patient data, diagnostic data and clinical information from other software capture systems and directly from ophthalmic devices. The Harmony RS has an absolute measurement tool which is derived from pixel spacing information provided by the source device and does not perform any automated image analysis. It provides line and area measurements as well as cup-disc ratio based on the user manually marking the images on the screen which are the same measurements performed by the Harmony. The Harmony also performs MPS which is not performed by Harmony RS.

Harmony RS and Harmony both allow standard viewing operations such as zoom in/out, flip/rotate, etc. and standard image enhancements such as contrast adjustment, and drawing tools. Harmony RS provides DICOM communication with other PACS as does Topcon Healthcare Solutions' Harmony (K182376). Harmony RS and Harmony both provide similar customizable print templates and archive and backup functionality.

The minor differences including the operating system, hardware requirements, system access, and measurement and analysis. The predicate device is operated on a MS Windows Server and supports the Chrome browser while the Harmony RS uses additional servers and browsers. The predicate software is used on a Windows XP/2000 PC while the Harmony RS operates on a Desktop PC operating Windows. The predicate device is available both on a desktop and web-based while the Harmony RS is only web-based.

The different technological characteristics of the devices do not raise new questions of safety and effectiveness. The differences in hardware requirements and system access are all system features that can be evaluated during software validation and verification and were primarily revised to allow the system to operate with newer hardware, browsers and operating systems.

The Harmony RS shares similar technological characteristics with the predicate device, both in terms of the manner in which images are captured, analyzed, and stored, as well as the operation of the device by the intended user. The software validation and verification shows that the Harmony RS performs as intended and supports substantial equivalence.

The following table compares the Harmony RS to the Harmony cleared in K182376.

TABLE 1
HARMONY REFERRAL SYSTEM SUBSTANTIAL EQUIVALENCE CHART

	Proposed Device	Predicate Device
Trade name	Harmony Referral System	Harmony
510(k) number	K210396	K182376
Manufacturer	Topcon Healthcare Solutions EMEA Oy	Topcon Healthcare Solutions, Inc.
Device Type	System, Image Management, Ophthalmic	System, Image Management, Ophthalmic
Regulation Description	Picture archiving and communications system	Picture archiving and communications system
Regulation Medical Specialty	Radiology	Radiology
Review Panel	Ophthalmic	Ophthalmic
Product Code	NFJ	NFJ
Regulation Number	892.2050	892.2050
Device Class	2	2
Indications for Use	Harmony Referral System (Harmony RS) is a comprehensive software platform intended for use in importing, processing, viewing, measurement and storage of clinical images and videos as well as in management and communication of patient data, diagnostic and clinical information and reports from ophthalmic diagnostic instruments through either direct connection with the instruments or through computerized networks. The	Harmony is a comprehensive software platform intended for use in acquisition or 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

	system neither performs any interpretations nor provides treatment recommendations.	instruments or through computerized networks.
Device Type	Software only	Software only
User Population	Trained professionals	Trained professionals
Platform / Operating System	Archive & application server: Debian Linux Integration server: Debian Linux, Windows Server Client: operating system supporting the following browsers: Microsoft Edge Chromium, Mozilla Firefox (two latest verssons)	Server: MS Windows Server 2012 R2 Client: operating system supporting the following browsers: Chrome
Hardware requirements	Processor performance level: i3 7th gen dual core, i5 4th gen quad core Ram: 4GB Full HD 1920x1080 resolution monitor Any operating system capable of running supported browser Network connection: 100 Mbps (recommended), 5 Mbps (minimum upload/download)	Window XP/2000 PC Monitor Keyboard Mouse
Web based access	Harmony Referral System is web-based system	Desktop and web-based access
Image Data compression	JPEG (lossy), JPEG 2000 (lossy, lossless), RAW (uncompressed) All files encapsulated inside DICOM format.	TIFF – uncompressed, PNG – lossless compress, JPEG – lossy compress, DICOM – lossy & lossless
Virtualization	Yes	Yes
User administration	centralized	centralized
HIS/EMR integration	Yes	Yes
DICOM	Yes	Yes

communication with other PACS		
Image processing	Standard image viewing operation such as zoom in/out, flip/rotate, etc. Standard image enhancement adjustment such as contrast adjustment, etc. Text annotation Line/circle/freehand drawing	Standard image viewing operation such as zoom in/out, flip/rotate, etc. Standard image enhancement adjustment such as contrast adjustment, etc. Text annotation Line/circle/freehand drawing
Measurement and analysis	• Scale to display pixel dimensions of the image • Line and area measurements • Cup-disc ratio	Perform line/area measurement with retinal images, Cup-Disc ratio, MPS
Reporting	available	available