June 4, 2026

Topcon Healthcare Solutions EMEA Oy
% Ian Boland
Senior Regulatory Affairs Specialist
Topcon Healthcare, Inc.
111 Bauer Dr.
Oakland, New Jersey 07436

Re: K253893
Trade/Device Name: Harmony Referral System with Harmony OCT Viewer (Octave)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: April 29, 2026
Received: April 30, 2026

Dear Ian Boland:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

BRADLEY S. CUNNINGHAM -S

Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253893_S002

Please provide the device trade name(s).

Harmony Referral System with Harmony OCT Viewer (Octave)

Please provide your Indications for Use below.

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.

The optional Harmony OCT Viewer module extends the indications with:
Harmony OCT viewer is intended for processing, viewing, analyzing, and providing measurements of clinical optical coherence tomography (OCT) and fundus images from any OCT acquisition device, in conjunction with the Harmony RS as a medical image communication system. It is not intended to provide treatment recommendations.

Harmony OCT viewer is indicated to be used as an aid in
• diagnosis and
• monitoring
by quantitative assessment of anatomic structures in the eye for various diseases.

For Topcon OCT devices, it uses reference databases from the original data capture device as a quantitative tool for the comparison to normal subjects.

Harmony OCT Viewer does not, in itself, provide diagnoses or perform treatment or active monitoring.

Please select the types of uses (select one or both, as applicable).

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

K253893 - Traditional 510(k) SUMMARY

Topcon Healthcare Solutions EMEA Oy.
Harmony Referral System with Harmony OCT Viewer (Octave)

Sponsor / 510(k) Owner
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Date Prepared: June 01, 2026

Trade Name of Device
Harmony Referral System 3.12 with Harmony OCT Viewer 1.0

Primary Predicate Device
Topcon Harmony Referral System (K210396)

Primary Predicate and Subject Device 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

Secondary Predicate Device
Topcon Corporation IMAGEnet6 Ophthalmic Data System (K241081)

Secondary Predicate Device 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 (Subsequent: OBO, HKI)

Intended Use / 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.

The optional Harmony OCT Viewer module extends the indications with:

Harmony OCT viewer is intended for processing, viewing, analyzing, and providing measurements of clinical optical coherence tomography (OCT) and fundus images from any OCT acquisition device, in conjunction with the Harmony RS as a medical image communication system. It is not intended to provide treatment recommendations.
Harmony OCT viewer is indicated to be used as an aid in

- diagnosis and
- monitoring

by quantitative assessment of anatomic structures in the eye for various diseases.
For Topcon OCT devices, it uses reference databases from the original data capture device as a quantitative tool for the comparison to normal subjects. Harmony OCT viewer does not, in itself, provide diagnoses or perform treatment or active monitoring.

Device Description
Harmony Referral System (Harmony RS), software version 3.12, 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 RS software collects and manages patient demographics, image data, and clinical reports from a range of approved medical devices. Harmony RS 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 RS 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.

Change Description

Harmony OCT Viewer:
Harmony Referral System's new optional module, Harmony OCT Viewer (also referred to as "Octave" as synonym), software version 1.0, is an advanced OCT viewer that is capable of replacing the original device viewer. This serves a few main purposes:

- Eliminate the need for additional software and licensing
- Avoid data duplication
- Combine the strengths of Harmony RS with IMAGEnet6 measurement functions for OCT data (data management portability with device software analytics)

Besides the addition of Harmony OCT Viewer, there have been several minor changes related to UI improvements, workflow enhancement, and connectivity, as summarized below.

Numerical data visualized in charts:
Selected Subjective and Objective refraction, Tonometry, and Pachymetry values can be visualized as trend charts allowing for easier understanding of changes over time by eye care providers and enabling multiple numeric values to be visible in the same view. Harmony imports these values from a connected EMR or directly from a compatible third-party device via HL7 standardized data. Harmony does not interpret or modify the imported data.

Hanging Protocols:
Hanging protocols are sets of specific cell layouts and examination item types that can be loaded to the examination viewer easily. These allow the eye care specialist to pre-configure certain examination types in a customized way to have the most informative combination of examination items to support their work. A hanging protocol contains the cell layout, content of each cell, view type, data sets, comparison rule, filters and enhancements and annotations. Hanging protocols do not generate new or modify existing data, they are a workflow improvement to pre-define customized view layouts of existing data.

Other:
There were several minor improvements made in the following categories:

- UI improvements
- Workflow enhancements
- Connectivity to devices and practice management systems
- Additional export options

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

Substantial Equivalence
The Harmony OCT Viewer, also referred to as Octave, is a device modification to the cleared Harmony Referral System (K210396) primary predicate device. Harmony OCT Viewer is an optional module within Harmony Referral System, and the technological characteristics of Harmony OCT Viewer are isolated within the module. The Harmony OCT Viewer has a comparable Intended Use and maintains the same fundamental scientific technology as the predicate device.

The Substantial Equivalence Summary Tables below illustrate the comparisons of the Harmony OCT Viewer to the primary and secondary predicate devices, and the following sections discuss and conclude substantial equivalence of the modifications.

Table 1: Indications for Use Comparison Chart

Subject Device Harmony Referral System with Octave – Harmony OCT Viewer	Primary Predicate Device Harmony Referral System (K210396)	Secondary Predicate Device IMAGEnet 6 (K241081)	Same or Different
Harmony RS (unchanged): 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	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	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	Different – the subject device merges the indications for use from the secondary predicate device with those of the primary predicate device. The indications for use for the subject device identify the device's role as an aid in diagnosis and monitoring with quantitative

Subject Device Harmony Referral System with Octave – Harmony OCT Viewer	Primary Predicate Device Harmony Referral System (K210396)	Secondary Predicate Device IMAGEnet 6 (K241081)	Same or Different
either direct connection with the instruments or through computerized networks. The system neither performs any interpretations nor provides treatment recommendations. Harmony OCT Viewer (new): Harmony OCT viewer is intended for processing, viewing, analyzing, and providing measurements of clinical optical coherence tomography (OCT) and fundus images from any OCT acquisition device, in conjunction with the Harmony RS as a medical image communication system. It is not intended to provide treatment recommendations. Harmony OCT viewer is indicated to be used as an aid in • diagnosis and • monitoring by quantitative assessment of anatomic structures in the eye for various diseases.	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.	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. Indications for Use of the combination of the Maestro2 in conjunction with IMAGEnet6 Maestro2 in combination with IMAGEnet 6 is indicated as an aid in the visualization of	analysis functionality, but this difference is determined to be substantially equivalent to the intended use of the predicate device as both the subject and predicate device are intended to be used in ophthalmic image management and analysis, and both utilize image data from the same capture devices. Furthermore, the predicate device shows the same image types as the subject device allowing for qualitative assessment by clinicians in both devices.

Subject Device Harmony Referral System with Octave – Harmony OCT Viewer	Primary Predicate Device Harmony Referral System (K210396)	Secondary Predicate Device IMAGEnet 6 (K241081)	Same or Different
For Topcon OCT devices, it uses reference databases from the original data capture device as a quantitative tool for the comparison to normal subjects. Harmony OCT Viewer does not, in itself, provide diagnoses or perform treatment or active monitoring.		vascular structures of the posterior segment of the eye including the retina, optic disc and choroid	

TABLE 2: TECHNOLOGICAL CHARACTERISTICS COMPARISON CHART

	Subject Device Harmony Referral System with Octave - Harmony OCT Viewer	Primary Predicate Device Harmony Referral System (K210396)	Secondary Predicate Device IMAGEnet 6 (K241081)	Same or Different
General				
Legal manufacturer	Topcon Healthcare Solutions EMEA Oy	Topcon Healthcare Solutions EMEA Oy	Topcon Corporation	Same as predicate.
Product Code	NFJ	NFJ	NFJ (OBO, HKI)	Same
Review Panel	Ophthalmic	Ophthalmic	Ophthalmic	Same
Technological Characteristic	Software as a Medical Device	Software as a Medical Device	Software as a Medical Device	Same

	Subject Device Harmony Referral System with Octave - Harmony OCT Viewer	Primary Predicate Device Harmony Referral System (K210396)	Secondary Predicate Device IMAGEnet 6 (K241081)	Same or Different
User Population	Trained professionals	Trained professionals	Trained professionals	Same
Acquisition				
Control of other medical devices	Not supported	Not supported	Limited to certain devices with supporting, intermediary capture software.	Same
Capture images directly	Not supported	Not supported	Not supported	Same
Import ophthalmic images	Supported	Supported	Supported	Same
Measurements				
Advanced OCT measurement functions	Yes	No	Yes	Different – Introduced in subject device to include comprehensive metrics. Primary predicate device only contains a basic measurement tool. Same in secondary predicate device.
IT Specifications				
Technology	Browser based	Browser based	Browser based	Same

	Subject Device Harmony Referral System with Octave - Harmony OCT Viewer	Primary Predicate Device Harmony Referral System (K210396)	Secondary Predicate Device IMAGEnet 6 (K241081)	Same or Different
Supported operating systems	Workstation: Windows 11 Supported browsers: Chrome, Mozilla Firefox, Microsoft Edge Chromium	Workstation: Any operating system capable of running supported browser. Supported browsers: Chrome, Mozilla Firefox, Microsoft Edge Chromium	Windows 10 Pro 64bit (at last clearance) or Windows 11 Pro 64bit (now)	Subject device supports Windows 11.

Substantial Equivalence Discussion

The Harmony OCT Viewer is a device modification to the cleared Harmony Referral System (K210396) predicate device. Technological characteristics of the device are unchanged except for the modifications as stated above. All technological characteristic modifications are a reimplementation from the cleared secondary predicate device. The Harmony OCT Viewer has comparable Indications for Use and maintains the same fundamental scientific technology as the predicate device.

The Harmony OCT Viewer measures the same basic ophthalmic features as the cleared Harmony Referral System in K210396. The changes applied to the Harmony Referral System since the clearance in K210396 do not change the intended users, intended patient populations, the type of imported, displayed and analyzed images, or that the Harmony Referral System 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 secondary predicate device, IMAGEnet 6, is manufactured by Topcon Corporation, and contains the same functionality introduced by Harmony OCT Viewer. Harmony OCT Viewer does not introduce new technology into the market but rather supplements the functionality of the existing OCT

Viewer in Harmony Referral System via the module, Harmony OCT Viewer, with features previously introduced by Topcon in IMAGEnet 6.

Harmony OCT Viewer changes the indications for use of the device to include enhanced quantitative analysis for aid in diagnosis and monitoring, but the device remains as safe and effective as the predicate with no new type of safety risks introduced by Harmony OCT Viewer.

Risk assessment was conducted on the Harmony OCT Viewer as per existing design control. Topcon performed software validation and verification activities to confirm that the Harmony OCT Viewer functions equivalently to the predicate Harmony.

Non-clinical performance testing was conducted on the Harmony OCT Viewer to verify and validate that the device is safe and effective for its intended use and indications for use. The Harmony OCT Viewer 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 (2024), 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 Harmony OCT Viewer is manufactured and tested in the same manner as the predicate 510(k) cleared device.

The addition of the Harmony OCT Viewer module does not raise new issues of safety and effectiveness. A comparison of technological characteristics (Table 2) and non-clinical performance testing demonstrate that the modified Harmony OCT Viewer device is substantially equivalent to the unmodified predicate device.

Conclusion

Comparison of technological characteristics and evaluation of non-clinical performance testing show that the modification to the Harmony Referral System to include the Harmony OCT Viewer module does 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. The changes to the indications for use and technological characteristics introduced by Harmony OCT Viewer do not impact substantial equivalence to its predicate. All functionality provided by Harmony OCT Viewer has already been present in a marketed, cleared device (Harmony, IMAGEnet6). The modifications to the cleared version of Harmony Referral System have been found to not raise concerns of safety or effectiveness and do not impact the substantial equivalence, thus the modified device is substantially equivalent to the predicate device.