September 28, 2018

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

Re: K182376
Trade/Device Name: Harmony
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: August 29, 2018
Received: August 31, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Bradley S. Cunningham -A

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182376

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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510(k) SUMMARY

Topcon Medical Systems, Inc.
Harmony

510(k) Owner
Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436
Phone: (201) 599-5208
Contact Person: James Lorkowski

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

Date Prepared: August 29, 2018

Trade Name of Device
Harmony

Common or Usual Name
System, image management, ophthalmic

Classification Name
21 C.F.R. 892.2050
Picture and Archiving communications system

Predicate Device
Topcon Corporation Synergy ODM (K151952)

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 Synergy ODM cleared in K151952. The differences between the new version and the currently cleared version are modifications to the GUI using a responsive design and a change to the front end platform from Microsoft Silverlight to HTML5.

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)

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

Substantial Equivalence
Harmony is substantially equivalent to Topcon's Synergy ODM cleared in K151952**.** Harmony has the same intended use and indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device**.** The intended use of the Harmony and intended use of the Synergy ODM cleared in K151952 are identical and both systems also have the identical indications for use statement.

Harmony has the same technological characteristics as the Synergy ODM (K151952). Both devices are software only image management systems which have the same acquisition, importing, viewing, measurement and analysis; network and security; print, archive and backup functionality.

Regarding acquisition, Harmony and the Synergy ODM (K151952) do not offer capture components. Both Harmony and Synergy ODM import digital

images, patient data, diagnostic data and clinical information from other software capture systems and directly from ophthalmic devices.

Regarding importing, Harmony and the Synergy ODM (K151952) allow importing and management of files and images from a range of ophthalmic diagnostic devices including DICOM files, image files of known format, video images, and printer files.

Regarding viewing, Harmony and the Synergy ODM (K151952) allow standard viewing operations such as zoom in/out, panning, etc. and standard image enhancements such as contrast and brightness adjustment, and drawing tools

Regarding measurement and analysis, Harmony and the Synergy ODM (K151952) provide line and area measurement capabilities and provide Cup to Disc ratio and MPS (Macular Photocoagulation Study) measurements.

Regarding network and security, both Harmony and the Synergy ODM (K151952) provide web-based access to all data files. Harmony and the Synergy ODM (K151952) provide DICOM communication with other PACS.

Regarding printing, Harmony and the Synergy ODM (K151952) provide similar customizable print templates. Regarding archiving and backup, Harmony and the Synergy ODM (K151952) include archive and backup functionality. The operating system for review stations running each of the systems is Windows XP or above. Harmony can also be executed on an iPad while Synergy ODM (K151952) can be used on a review station with Mac OS X operating system. This minor difference does not impact substantial equivalence.

Modifications were made as the front end platform was changed from Microsoft Silverlight to HTML5 and the design of the GUI was changed to a responsive design. Software documentation is provided in Section VIII in support of these changes. It is not believed that any of these changes impact the substantial equivalence of the Harmony to the prior Synergy ODM.

In conclusion, Harmony shares similar technological characteristics with the predicate device, both in terms of the manner in which images are imported, analyzed, and stored, as well as the operation of the device by the intended user.

Conclusion

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 Synergy ODM are minor and do not impact the substantial equivalence.