



Food and Drug Administration  
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October 1, 2015

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

Re: K151952  
Trade/Device Name: Synergy ODM  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture Archiving and Communications System  
Regulatory Class: Class II  
Product Code: NFJ  
Dated: September 4, 2015  
Received: September 8, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kesia Y. Alexander -S**

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

## Indications for Use

510(k) Number (if known)

K151952

Device Name

Synergy ODM

Indications for Use (Describe)

Synergy ODM 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. Synergy ODM**

#### **510(k) Owner**

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#### **Submission Correspondent**

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Date Prepared: July 13, 2015

#### **Trade Name of Device**

Synergy ODM

#### **Common or Usual Name**

System, image management, ophthalmic

#### **Classification Name**

21 C.F.R. 892.2050  
System, image management, ophthalmic

#### **Predicate Device**

Topcon Corporation Synergy ODM (K132667)

#### **Intended Use / Indications for Use**

Synergy ODM 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**

Synergy ODM is a modification to Synergy ODM cleared in K132667. The key differences between the cleared product and the one that is the subject of this 510(k) are minor modifications to the GUI, addition of a mobile GUI, minor workflow enhancements, additional measurements based on existing line and area measurement tools, minor enhancements to the data acquisition and export functionality, addition of two new reports, minor enhancements to external access to Synergy ODM, performance enhancements to decrease start up time, enhancement to external interfaces, changes to configuration options and tools which are not accessible to the end user, modifications required to maintain compatibility with external products, modification to tools which are not accessible to the user, and bug fixes.

Synergy ODM is a software platform that collects, processes, measures, analyzes, stores, and manages patient data and clinical information. Synergy ODM is used together with a number of computerized digital imaging devices. In addition, Synergy ODM software collects and manages patient demographics, image data, and clinical reports from a range of medical devices. Synergy ODM enables a real-time review of diagnostic patient information at a PC workstation. Synergy ODM also includes an internet-browser-based user interface to allow authorized users to access, view, create reports, and analyze patient and examination data saved in a centralized database. The system utilizes dual level authentication and 128-bit encryption to ensure secure networking environment.

### **Performance Data**

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

### **Substantial Equivalence**

Synergy ODM is substantially equivalent to Topcon's Synergy ODM cleared in K132667. Synergy ODM has the same intended use and indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device.

Synergy ODM has the same technological characteristics as the Synergy ODM cleared in K132667. 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, Synergy ODM and the Synergy ODM cleared in K132667 do not offer capture components. Both versions of Synergy ODM (the Synergy ODM in this 510(k) and the Synergy ODM cleared in K132667) import digital images, patient data, diagnostic data and clinical information from other software capture systems and directly from ophthalmic devices. Minor modifications were made to data acquisition functionality to allow additional data formats and types, however, these were minor modifications that do not have a significant impact on the acquisition functionality and do not impact substantial equivalence to the prior version of Synergy ODM.

Regarding importing, both versions of Synergy ODM 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, both versions of Synergy ODM allow standard viewing operations such as zoom in/out, panning, etc. and standard image enhancements such as contrast and brightness adjustment, and drawing tools. The modifications to the cleared Synergy ODM included minor improvements to the GUI and addition of a mobile GUI. Neither of these changes have any impact on the substantial equivalence.

Regarding measurement and analysis, both versions of Synergy ODM provide line and area measurement capabilities and provide Cup to Disc ratio and MPS (Macular Photocoagulation Study) measurements. There were minor enhancements of the existing measurement capabilities using existing linear and area measurement tools including the addition of Circle Measurement and PDT measurement. However, although these are listed as new measurements types, they use existing line and area measurement functionality and no new measurement tools were introduced.

Regarding network and security, both versions of Synergy ODM provide web-based access to all data files. Both versions of Synergy ODM provide DICOM communication with other PACS. Minor enhancements were made to simplify access to Synergy ODM and improve security features but these changes do not impact the substantial equivalence.

Regarding printing, both versions of Synergy ODM provide similar customizable print templates. The revised version of Synergy ODM includes the addition of two reports based on existing report templates. Regarding archiving and backup, both versions of Synergy ODM include archive and backup functionality. The operating system for review stations running each of the systems is Windows XP or above. Both versions of Synergy ODM can also be executed on review stations with Mac OS X operating system.

The other modifications to the system were very minor in nature and included minor workflow enhancements, minor improvements in data export to allow export of multiple images in a zipped file, performance improvements to decrease start up time, enhancements of external interfaces to allow support of additional data formats, modifications to internal configuration options not available to end user, minor modifications to allow continued compatibility with external products and tools, and fixes to known bugs. It is not believed that any of these changes impact the substantial equivalence to the prior version of Synergy ODM.

In conclusion, Synergy ODM 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.

In summary, Topcon's Synergy ODM has the same intended use and indications for use as the previously cleared predicate device. In addition, Synergy ODM 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.