DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 8, 2017

Optos Plc
% Mr. Randy Prebula
Partner
Hogan Lovells U.S. LLP
555 13th Street NW
Washington, DC 20004

Re: K162039
Trade/Device Name: OptosAdvance 4.0 (OA4) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: December 29, 2016
Received: December 29, 2016

Dear Mr. Prebula:

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,

Denise L. Hampton -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K162039

Device Name

OptosAdvance 4.0

Indications for Use *(Describe)*

OptosAdvance 4.0 is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports, videos, and measurement of DICOM-compliant images.

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

Optos Plc's OptosAdvance 4.0 Software

In accordance with 21 CFR §807.92 the following summary of information is provided:

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Date Prepared: July 22, 2016

DEVICE:

Trade Name: OptosAdvance 4.0 (OA4) Software

Common or Usual Name: Picture Archiving and Communication System (PACS)

Classification Name: System, Image Management, Ophthalmic
(per 21 C.F.R. § 892.2050)

Device Classification: Class II

Product Code: NFJ

LEGALLY MARKETED PREDICATE DEVICES

Predicate Device Name: OptosAdvance Software
510(k) Number: K113696
Manufacturer: Optos Plc

Predicate Device Name: Synergy ODM
510(k) Number: K151952
Manufacturer: Topcon Medical Systems, Inc

INTENDED USE / INDICATIONS FOR USE

OptosAdvance 4.0 is a standalone, browser-based software application intended for use by healthcare professionals to import, store, manage, display, analyze and measure data from ophthalmic diagnostic instruments, including: patient data, diagnostic data, clinical images and information, reports, videos, and measurement of DICOM-compliant images.

DEVICE DESCRIPTION

The OA4 software application provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The OptosAdvance user interface follows typical clinical workflow patterns to process, review, and analyze digital images.

The key features of OptosAdvance 4.0 include the ability to:

- Acquire, store, retrieve and display DICOM image data;
- Access patient data securely;
- Search patient studies and select images for closer examination;
- Interactively manipulate an image to visualize anatomy and pathology;
- Select multiple images for comparison;
- Annotate, tag and record selected views;
- Measure distance (linear) and area of DICOM images;
- Manage, backup and archive data;
- Import and export data to network storage devices;
- Securely access and transfer data; and
- Output selected views to printers.

The software relies on images being provided to a specified network path on the OptosAdvance Server by the connected ophthalmic device (Scanning Laser Ophthalmoscope, Fundus Camera, Optical Coherence Tomography unit, etc.) in a DICOM-compliant format. The software will then place the image and associated data on the network storage unit in a format which will allow the image to be available via a securely connected web browser. Locally archived studies will be securely pushed to the remote archive server for storage. The archive in the remote secure server serves as disaster recovery storage as well as access to the patient history.

PERFORMANCE TESTING

OptosAdvance 4.0 is designed, developed and tested according to the software development lifecycle process implemented at Optos Plc. Software testing was completed to ensure the new feature operates according to requirements and without impact to existing functionality. Testing included verification, validation, and evaluation of previously acquired medical images.

For additional reassurance, equivalence tests were performed to verify that the OptosAdvance 4.0 software application provides equivalent measurements by loading DICOM objects that contain features with known dimensions, displaying these objects to the user, having the user measure these features, and comparing their measurement with the known dimensions.

Risk Management

Each risk pertaining to OptosAdvance 4.0 has been individually assessed to determine if the benefits outweigh the risk. Every risk has been reduced as low as possible and has been evaluated to have a probability of occurrence of harm of no more than "Remote". All risks for the updated software feature were collectively reviewed to determine if the benefits outweigh the risk.

The proposed device has been designed and tested taking into account potential cybersecurity risks, to ensure confidentiality, integrity, availability and accountability.

Standards Compliance

The OptosAdvance 4.0 software complies with the following voluntary standards:

Standard No.	*Standards organization*	*Standards Title*
PS 3.1 - 3.20 (2014c)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set
14971:2012	AAMI / ANSI / ISO	Medical Devices – Applications of risk management to medical devices
62304:2006	AAMI / ANSI / IEC	Medical Device Software - Software life cycle processes
62366-1 Edition 1.0 2015-02	IEC	Medical Devices – Part 1: Application of usability engineering to medical devices

Clinical Data

OptosAdvance 4.0 is a PACS system that processes DICOM data. Therefore, any clinical comparison with a predicate that operates per the same DICOM standard will produce the same result. Thus, clinical studies are not required to support the subject device's safety and effectiveness; the non-clinical objective test methods used for evaluation demonstrate that the software's performance is equivalent to that of the legally marketed predicates. Nevertheless, the anticipated clinical equivalence was confirmed with a clinical case.

SUBSTANTIAL EQUIVALENCE

The proposed device is of the same type, common name, classification, and product code as the cleared predicate devices. The devices have the same intended use, and the indications for use of OptosAdvance 4.0 are very similar to the indications for use of the predicate software devices.

OptosAdvance 4.0 is also functionally equivalent to these devices. The proposed and predicate devices are all software-only image management systems with similar acquisition, importing, viewing, measurement and analysis, network and security, print, archive and backup functionalities. The minor technological differences between OptosAdvance 4.0 and its predicate devices raise no new issues of safety or effectiveness, as described below.

The key difference between the predicate OptosAdvance software (K113696) and the new version of OptosAdvance is the introduction of features to measure distance (linear) and area of DICOM images. The predicate Synergy ODM device (K151952) provides such line and area measurement capabilities, so the inclusion of this feature in the subject software does not raise different questions of safety or effectiveness.

The devices also differ slightly in their approach to data management backup and archiving. While the cleared Synergy ODM uses locally installed customized software to allow the user to view images stored on the local or networked computer system, OptosAdvance 4.0 uses the computer system's web browser with no other software installation required to allow the user to view DICOM-compliant images stored on the server. The verification and validation testing for the subject software covered the comparison of images on custom software and the web client, which were found to display at the same resolution and clarity. OptosAdvance 4.0 also allows the user to connect to a remote secure server to allow greater archiving flexibility. The only minor difference to OptosAdvance 4.0 from Synergy ODM in this respect is that the user can set up an HTTPS connection to the remote server to transfer data to and from the archive, providing greater flexibility on storage. A similar mechanism exists in the Synergy ODM software, where data can be stored on an external network location and accessed externally. In order to do this remotely in the OptosAdvance 4.0 software, a secure protocol is introduced to protect data integrity.

CONCLUSION

OptosAdvance 4.0 has the same intended use and indications for use as the Optos predicate device (K113696), and has very similar principles of operation and technological characteristics as both predicate devices (K113696 and K151952). Any minor differences noted have been explained and do not raise any different questions of safety or effectiveness when the software is used as labelled. The implemented design controls, risk management activities, labelling, and performed tests (software verification & validation) demonstrate the safety and efficacy of the device in comparison to the predicates. Therefore, based on the comparison and test data, the OptosAdvance 4.0 software application is as safe and effective as, and substantially equivalent to, the predicate devices.