K113696

MAY 25 2012

510(k) SUMMARY

Optos' Optos Advance Software

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sponsor: Optos plc
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Date Prepared: 16 December 2011

Name of Device: Optos Advance

Common Name: Picture Archiving and Communications System

Classification: Picture Archiving and Communications System (per 21 C.F.R. § 892.2050)

Product Code: NFJ

Device: System, Image Management, Ophthalmic Device

Predicate Device: Carl Zeiss Surgical GmbH FORUM Software (K090439)

Indications for use

The Optos Advance Software is a web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data, videos and images from computerized diagnostic instruments or video documentation systems.

Technological Characteristics

The Optos Advance Software is an image review application that allows the user to view DICOM compatible images. The Optos Advance Software organizes the digitized images into studies and sessions. The digitized studies and sessions may be viewed by using an overall or bilateral display (*i.e.*, display provides comparisons between old and new images). The software also allows

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physicians or technicians to create on-line notes with the ability to zoom in or out (*i.e.,* enlarge or decrease magnification of images) and annotate such images with arrows or text boxes to highlight areas the user determines by training and experience to be of interest. The Optos Advance Software does not automatically highlight, annotate, or otherwise alter the images. In addition, the digitized studies and sessions and on-line notes may be viewed, archived on a central file server, or electronically shared in a secure manner with other health care professionals.

The Optos Advance Software allows the user to interface a Scanning Laser Ophthalmoscope, Fundus Camera, OCT or other DICOM compliant diagnostic camera with the Optos Advanced Software via a secure network connection to the Optos Advance Server. The server has a watchdog service which processes the DICOM information sent via the network. The information is then processed and placed in local storage on the Optos Advance Server. The data is obfuscated at the server side to protect any patient information transferred.

The Optos Advance Software does not require any customized software installed on the client PC. The images, annotations and DICOM data are all stored on the Optos Advance Server, which handles the archiving, reporting, and retrieval of the data. This server can be set up remotely over an HTTPS connection which allows secure remote transfer of the stored data for archive purposes.

Performance Testing

A full software and system verification and validation was performed as per the Software Development Lifecycle Process in Optos PLC.

Substantial Equivalence

The Optos Advance Software has the same intended use and substantially similar indications for use as the cleared Carl Zeiss Surgical GmbH FORUM Software (K090439). Minor differences in technological characteristics allow the user to access the software from any web enabled browser without the need for any customizable software installed on their personal computer and to archive their data to a remote server for retrieval over an HTTPS protocol driven server. Both Optos Advance and FORUM Software are intended for the review, storage and retrieval of images and image data supplied by ophthalmic medical devices. Thus, the minor differences between the Optos Advance Software and its predicate device raise no new questions of safety and effectiveness and the Optos Advance is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Optos Plc
c/o Mr. Howard M. Holstein, Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington DC 20004

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Re: K113696
Trade/Device Name: Optos Advance Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: May 8, 2012
Received: May 8, 2012

Dear Mr. Holstein:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Jessica Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113696

Device Name: Optos Advance Software

Indications for Use:

The Optos Advance Software is a web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data, videos and images from computerized diagnostic instruments or video documentation systems.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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