510(K) SUMMARY

OIS EYESCAN PORTABLE MODULAR IMAGING SYSTEM

510(k) Number K 111006

Applicant's Name: Ophthalmic Imaging Systems
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Manufacturing Site: 221 Lathrop Way
Suite I
Sacramento, CA 95815
USA

Date Prepared: December 31, 2010

Trade Name: OIS Symphony

Classification Name: CFR classification section 892.2050 (product Code NFJ).

Classification: Class II Medical Device

Predicate Device:

OIS Symphony Image Management System is substantially equivalent to the following predicate devices:

(1) Zeiss Forum (K090439) Manufactured by Carl Zeiss Meditec Inc. is intended as a software system in storing, managing, and displaying patient data, diagnostic data, videos, and images from computerized diagnostic instruments through networks.

(2) Nidek Advanced Vision Information System (NAVIS) (K013694) manufactured by Nidek is a computer technology software that collects, stores, and maintains patient data information; providing real-time diagnostic patient information from a number of diagnostic ophthalmic instruments at any PC workstation. Navis contains core software that can be, augmented by additional software modules, supporting the various applications used clinically.

(3) Synergy (K093313) Manufactured by Topcon Medical Systems Inc, is a comprehensive software platform intended for use in acquisition or 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.

Comparison of Technology with Predicates:

The OIS Symphony employs the same, or similar, technological characteristics as the predicate devices.

Device Description:

The OIS Symphony System is a software solution for the display, management, archive, interface and integration of ophthalmic device reports, images and data. OIS Symphony consists of image display via Symphony Web, Image Import via Symphony Import and integration of imaging performed in OIS WinStation.

OIS Symphony is a software solution consistent with the predicate devices listed herein, using databases for patient demographics, server and other systems of intercommunication with hospital systems via HL7 and DICOM to provide to clinicians a single image viewing and management solution of images imported from various contributing devices throughout the clinical environment.

Symphony provides the ability to review data from any network-connected computer, and is protected by appropriate security login which permits only authorized user access. Symphony uses 256 bit or greater encryption via secure socket layer (SSL) to assure a network environment which is secure.

Intended Use / Indication for Use:

OIS Symphony is a comprehensive software platform for the import, integration and review of patient data and clinical information in an eye care environment. OIS Symphony allows for the collection, management, enhancement and review of the patient demographics, image data, diagnostic data and clinical reports from a variety of medical devices through either a direct connection with the instruments or through computerized networks.

Performance Standards:

None. There are no mandatory performance standards for this type of device.

Test Data:

The OIS Symphony System has been subjected to extensive performance testing and validation before release. Final testing of OIS Symphony included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. See Section 9 for statement and declaration of conformity.

Substantial Equivalence:

OIS Symphony is a comprehensive platform that collects, processes, measures, analyzes, and manages patient data and clinical information in an eye care environment. OIS Symphony provides a real time viewing environment for the collection and management of the patient demographics, image data, and clinical reports from a variety of approved medical devices, either directly or via a computer network. Similarly the predicate devices, including Zeiss Forum, NAVIS, and Topcon Synergy, are platforms for the import, acquisition, storage, and review of clinical images and tests of the eye, produced via a network or direct connection to the clinical instrument. The intended operators of OIS Symphony, similar to those of the predicate devices, are physicians (ophthalmologists), optometrists, ophthalmology technicians/ photographers. OIS Symphony and the predicate devices are used in environments that include hospital departments, ophthalmology clinics, and related medical facilities.

Conclusions:

The conclusions drawn from the above comparison to predicate devices is that OIS Symphony is substantially equivalent in safety and effectiveness to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ophthalmic Imaging Systems
% Ms. Andrea Ambrose
Quality Manager
221 Lanthrop Way, Suite I
Sacramento, CA 95864

MAY 18 2011

Re: K110006
Trade/Device Name: OIS Symphony Image Management System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: NFJ
Dated: May 11, 2011
Received: May 16, 2011

Dear Ms. Ambrose:

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,

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

510(k) Number (if known): k110006

Device Name: OIS Symphony

Indications for Use:

OIS Symphony is a comprehensive software platform for the import, integration and review of patient data and clinical information in an eye care environment. OIS Symphony allows for the collection, management, enhancement and review of the patient demographics, image data, diagnostic data and clinical reports from a variety of medical devices through either a direct connection with the instruments or through computerized networks.

Prescription Use √ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use ___ (Optional Format Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number k110006