K120238

optovue

APR - 3 2012

510(k) Summary

Optovue, Incorporated

This 510(k) summary for the RTVue is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:

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Device Information

Classification: Class II

Trade Name: RTVue XR

Common Name: Optical Coherence Tomography (OCT)

Classification Name: Ophthalmoscope, a-c powered (21 C.F.R. § 886.1570)

Predicate Devices

510(k) **K101505** RTVue with NDB Optical Coherence Tomography (OCT)

Purpose of the Special 510(k) notice

The RTVue XR OCT is an upgrade to the current cleared device RTVue with NDB (**K101505**) with a new line scan camera for faster image acquisition.

Intended Use

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The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
The RTVue XR with Normative Database is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

Technological Characteristics

The RTVue XR is a non-invasive diagnostic device for imaging the cornea, anterior chamber, and retinal tissue structure with micrometer range resolution. The RTVue XR OCT is based on the same Optical Coherence Tomography (OCT) technology used in its predicate device, RTVue with NDB OCT.
The RTVue XR is a computer controlled ophthalmic imaging system. The device scans the patient's eye using a low coherence interferometer to measure the reflectivity of the retinal tissue. The cross sectional retinal tissue structure is composed of a sequence of A-scans. It has a traditional patient and instrument interface like most ophthalmic devices. The computer has a graphic user interface for acquiring and analyzing the image.

RTVue XR offers three scan types: Retina, Glaucoma, and Cornea. For the Cornea scan, a lens must be attached to the front of the device for proper scanning. This lens is called the CAM (Cornea Anterior Module-cleared under K111505)

The upgrade of the line scan camera is designed to **provide faster image acquisition.** The RTVue XR is an updated version of RTVue with NDB that operates at ~70,000 A-lines per second while the RTVue-100 operates at ~27,000 A-lines per second. The RTVue XR machines will be equipped with new line-scan cameras capable of operating at ~70,000 A-lines per second while delivering equivalent imaging results as the older generation RTVue line-scan cameras operating at ~27,000 A-lines per second.

Performance Data

Elliot lab Certification Testing and Report (ref: R64363 Rev.3 and R63863 Rev. 4) in accordance to IEC 60601-1 Amendment 1 and 2 and IEC-60601-1-2. In addition a Bench test was also performed, with the results for comparison of the RTVue XR with the predicate device RTVue with NDB. The RTVue XR meets the safety and stability requirements of IEC 60601-1and IEC-60601-1-2 as well as the bench test requirements results.

Substantial Equivalence

The RTVue XR has the same intended use and similar indications, principles of operation, and technological characteristics as the **RTVue with NDB OCT**. The minor difference in the RTVue XR OCT is **a new line scan camera for faster image acquisition and this upgrade** does not raise any new questions of safety or effectiveness. Performance data demonstrates that the **RTVue XR** is as safe and effective as **RTVue with NDB OCT**. Thus, the **RTVue XR** is substantially equivalent to its predicate devices.

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

Optovue, Inc
c/o Mr. John Talarico
VP Regulatory and Clinical Affairs
45531 Northport Loop W.
Fremont, CA 94538

APR - 3 2012

Re: K120238
Trade/Device Name: RTVue XR OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: February 23, 2012
Received: February 27, 2012

Dear Mr. Talarico:

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,

for Kesia Alexander

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

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Indications for Use Statement

510(k) Number (if known): K120238

Device Name: RTVue XR

Indications for Use:

The RTVue XR with Normative Database is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician.
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Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 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

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