K103266

510(k) Summary

Optovue, Incorporated

JUN - 3 2011

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

General Information

Manufacturer: Optovue, Inc.
45531 Northport Loop West,
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668
Registration No.: 3005950902

Contact Person: John J. Talarico
VP Regulatory and Clinical Affairs
Optovue, Inc.
Phone: (510)623-8868 x209
e-mail: john_talarico@optovue.com

Device Information

Classification: Class II

Trade Name: iStand

Common Name: Optical Coherence Tomography (OCT)

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

Predicate Devices

510(k) K091404 iVue 100 Optical Coherence Tomography (OCT)

Purpose of this Traditional 510(k) notice

The iVue OCT with optional iStand is an optional accessory addition to the iVue OCT System. Its purpose is to provide mobility and patient exam accessibility for the system.

Intended Use

The iVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, optic disk, cornea, and anterior chamber of the eye as an aid in the diagnosis and management of ocular diseases. The iStand is an optional accessory to the iVue which allows qualitative in-vivo imaging in cooperative, supine patients.

Technological Characteristics

The iVue is a non-invasive diagnostic device for imaging the cornea, anterior chamber, and retinal tissue structure with micrometer range resolution. The iVue OCT with iStand is based on the same Optical Coherence Tomography (OCT) technology used in its predicate device, iVue OCT.

K103266

The iVue OCT with iStand is a **mobile** 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 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.

iVue offers three scans: 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-L (Cornea Anterior Module – Long).

The optional addition of the **iStand** is designed to **provide effective transportation of the iVue OCT when used under normal operational conditions.** The mobile floor stand (iStand) with boom arm allows the iVue OCT System the ability to operate in different locations and allows the patient to be in a supine position during examination.

Safety

The addition of the iStand accessory to the iVue OCT system is to provide mobility and patient exam accessibility for the system; the energy level and safety of the device are not affected.

Effectiveness

The substantial equivalence comparison to the predicate device presented in this premarket notification with regard to intended use, operating principle, function, material, and energy source are unchanged on the effectiveness of the device.

Performance Data

TUV Certification Testing and Report (ref: 30883520.011) was performed in accordance to IEC 60601-1 Amendment 1 and 2. The iVue OCT with iStand meets the stability requirements of IEC 60601-1.

Substantial Equivalence

The iVue OCT with iStand has the same intended use and similar indications, principles of operation, and technological characteristics as the **iVue OCT**. The minor differences in the **iVue OCT with iStand's mobility** do not raise any new questions of safety or effectiveness. Performance data demonstrates that the **iVue OCT System with the iStand** is as safe and effective as **iVue OCT**. Thus, the **iVue OCT with the iStand** is substantially equivalent to its predicate devices.

45531 Northport Loop W, Fremont, CA 94538 Phone: (866) 344.8948; (510) 623-8868 Fax: (510) 623.8668

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
Vice President Regulatory and Clinical Affairs
45531 Northport Loop West
Fremont, CA 94538

JUN 3 2011

Re: K103266
Trade/Device Name: iStand
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: May 27, 2011
Received: May 31, 2011

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,

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): K103266

Device Name: iStand

Indications for Use:

The iVue is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, optic disk, cornea, and anterior chamber of the eye as an aid in the diagnosis and management of ocular diseases. The iStand is an optional accessory to the iVue which allows qualitative in-vivo imaging in cooperative, supine patients.

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

510(k) Number K103266

45531 Northport Loop W, Fremont, CA 94538 Phone: (866) 344 8948; (510) 623-8868 Fax: (510) 623.8668