510(k) Summary
Optovue iVue 500
K133892

MAR 1 9 2014

This 510(k) summary for the iVue 500 is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Category	Comments
Sponsor:	Optovue, Inc. 2800 Bayview Pkwy Fremont, CA 94538
Correspondents:	Michael Sarrasin, Esq., VP, Regulatory Affairs and Quality Assurance michael_sarrasin@optovue.com
Manufacturer:	Optovue, Inc. 2800 Bayview Parkway Fremont, CA 94538
Device Common Name:	Optical Coherence Tomography (OCT) System
Device Proprietary Name:	iVue 500
Device Classification	Cl II, HLI, 21 CFR §886.1570
Predicate Device	iVue with NDB, K121739
Predicate Device Manufacturer	Optovue, Inc.
Predicate Device Classification	Cl II, HLI, 21 CFR §886.1570

Date Summary was Prepared: January 7, 2014

Device Description: The iVue 500 is a modification of its predicate device iVue with Normative Database (NDB) (K121739). The intended use, system performance, sub-assemblies, and key components of the iVue with NDB are all the same as the iVue with NDB. The intent of this redesign was to make the iVue a more compact desktop device, so it is more convenient to use and set-up in a typical office. Additionally operation via touchscreen or mouse driven technology, makes it simpler for a technician to use.

Intended Use: The iVue 500 with normative database is an optical coherence tomography system intended for in vivo imaging, axial cross-sectional, three-dimensional imaging and measurement of anterior and posterior ocular structures.

Indications for Use: The iVue 500 with normative database is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial cross-sectional and three-dimensional imaging and measurement of anterior and posterior ocular structures.

including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, and anterior chamber of the eye. The iVue 500 with normative database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue 500 with normative database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population. (identical to predicate device)

Technological Characteristics: The iVue 500 is a non-invasive device for imaging the cornea, anterior chamber, and retinal tissue structure with micrometer range resolution.

Comparison to Predicate Device: The iVue 500 is a modification of its predicate device iVue with Normative Database (NDB) (K121739). The intended use, system performance, sub-assemblies, and key components of the iVue 500 with NDB are all the same as the iVue with NDB.

Device	Predicate	Current
510(k) Reference:	K121739	K133892
Intended Use:	The iVue with Normative Database is an optical coherence tomography system intended for in vivo imaging, axial cross-sectional, three-dimensional imaging and measurement of anterior and posterior ocular structures.	Same
Device Description:	Optical Coherence Tomography (OCT) System	Same
Device Common Name:	Optical Coherence Tomography (OCT) System	Same
Device Classification:	Class II HLI (21 CFR 886.1570)	Same
Manufacturer:	Optovue, Inc.	Same

Summary of Testing: Testing was performed to verify design, and showed there were no new questions of safety or effectiveness with the subject device. This testing included electrical safety testing, electrical emissions testing, as well as bench. Bench testing demonstrated that the

iVue 500 is able to align to appropriate working distance on both left and right eyes within the predefined acceptance criteria.

The bench test of iVue 500 utilizing 2 model eyes provides evidence that the software assisted motorized iVue 500 is able to complete the initial alignment of moving the scanner head to working position and to align the scanner head with the pupil within ±1mm tolerance. These are the general requirements to align a scanner to be able to capture an OCT image. Also the iVue 500 is able to move scanner head between right and left eyes.

Retina Mode	Range	Average	Criteria	Results
Working distance	20.3-22mm	21.3	+/- 1mm	Pass
centering	0-.2mm	n/a	+/- 1mm	Pass
Pupil distance	66.1-66.6mm	n/a	+/- 1mm	Pass

Cornea Mode	Range	Average	Criteria	Results
Working distance	16.4-17.3mm	16.7	+/- 1mm	Pass
centering	0-.1mm	n/a	+/- 1mm	Pass
Pupil distance	65.7-66.8mm	n/a	+/- 1mm	Pass

Conclusion: As described in this 510(k) Summary, all necessary testing and analyses were completed on the iVue 500 to ensure that the device is substantially equivalent to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 19, 2014

Optovue, Inc.
% Mr. Michael Sarrasin, Esq.
Vice President, Regulatory Affairs & Quality Assurance
2800 Bayview Drive
Fremont, CA 94538

Re: K133892
Trade/Device Name: iVue 500
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: February 19, 2014
Received: February 20, 2014

Dear Mr. Sarrasin:

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 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. 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,

Deborah L. Falls -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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133892

Device Name

iVue 500

Indications for Use *(Describe)*

The iVue 500 with normative database is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial cross-sectional and three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, and anterior chamber of the eye. The iVue 500 with normative database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue 500 with normative database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Rahul K. Ram -S (Affiliate)
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