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K130656

510(k) Summary

Optovue, Inc.

JUL 0 3 2013

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

General Information

Manufacturer:

Optovue, Inc.
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Contact Person:

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Optovue, Inc.
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Device Information

Trade Name: iFusion

Common Name: Ophthalmic Cameras
Optical Coherence Tomographers

Classification Name: AC-powered Ophthalmic Camera (21 C.F.R. § 886.1120)

Classification: Class II

Product Code: HKI
OBO

Predicate Devices

1. 510(k) **K121739** iVue with Normative Database - Optovue
2. 510(k) **K122572** iCam Fundus Camera - Optovue

Purpose of the Special 510(k) notice

iFusion is a combination of the cleared **iVue with NDB** (K121739)("iVue") and the cleared **iCam Fundus Camera** (K122572)("iCam") on a shuttle platform, called the iShuttle. The

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iShuttle mounts to a joystick assembly using a central nut and bolt and four adjustable set screws. The iShuttle consists of a sliding metal plate supporting the iVue and the iCam. The iShuttle travels on tracks fitted to the X-Y-Z joystick assembly which helps position the iVue and the iCam devices. A release button is located at the front of the iShuttle to lock the iShuttle in position for the iVue and the iCam device. The iVue and the iCam can be switched in position by pressing on the release button to unlock the iShuttle platform, then the iVue or the iCam can be pushed to slide to an opposite end until it is locked into position. In addition, the software of the iFusion system is created to allow the user to switch between the iVue and the iCam programs with the same computer. The iVue and the iCam programs use the same data communication and programming storage with a single shared database.

Intended Use

iCam Fundus Camera (K122572) – The iCam is a non-contact, high resolution digital imaging device which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. The iCam takes digital images of the posterior and external structures of the eye without the use of a mydriatic agent and is intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health. iCam provides images only and does not provide any diagnostic, pathological analysis or classification of ocular health or disease.

AND

iVue with Normative Database (K121739) – The iVue is a non-contact, high resolution optical coherence tomography system intended for in vivo imaging, axial cross-sectional, 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 with Normative Database is a quantitative tool for comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects.

Indications for Use

The iFusion connects the iCam (K122572) and iVue (K121739) devices via a sliding bracket mechanism (iShuttle), to facilitate switching between the two devices. The iShuttle provides position adjustment ability of the iCam or iVue device during use.

The iFusion interfaces with the iCam and iVue devices to enable the operation of the iCam and iVue devices from one computer unit.

Technological Characteristics

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iFusion combines the cleared **iVue with NDB** (K121739) and the cleared **iCam Fundus Camera** (K122572). The iVue and iCam are mounted onto the iShuttle to form a new device called the iFusion.

iFusion has the same technological characteristics as its component predicate devices **iVue** and **iCam** except the addition of the iShuttle. The iShuttle is a metal bracket that slides the iVue and the iCam into position for operation and does not affect the functionality of either system. The iShuttle merely allows the user to select between the devices. Minor software changes were made to allow the users to switch between the iVue and the iCam program in the iFusion software, and to export images and data from iCam to iVue.

The iShuttle does not affect the functionality of the systems. Software verification/validation testing has shown that the minor software changes did not raise any question about safety and effectiveness. Therefore, the iFusion is substantially equivalent to its predicate devices.

Performance Data

The iFusion system has the same intended use and indications for use as the predicate devices, namely the **iVue** and the **iCam**. The technological characteristics and the principles of operation for its component predicate devices are the same.

There is no significant change of the **iVue with NDB** and the **iCam** previously cleared under **K121739** and **K122572,** respectively. The safety and effectiveness of these devices have not changed.

iFusion has been designed and tested to applicable safety standards and Optovue SOPs, including design controls and risk analysis. Verifications and validations were performed for mechanical and functional testing according to IEC 60601-1 and 60601-1-2 for the new iShuttle bracket and the software changes.

The results demonstrated that the changes in iFusion did not affect the intended use or alter the fundamental technological characteristics of the predicate devices and that the **iFusion** is substantially equivalent to its predicate devices.

Conclusion

The iVue with NDB and the iCam of the iFusion have the same intended use and indications for use, same principles of operation, and same technological characteristics as the cleared devices. Therefore, the **iFusion** is substantially equivalent to its predicates.

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

July 3, 2013

Optovue, Inc.
% Mr. Bill Jackson
VP Regulatory & Quality Assurance
2800 Bayview Drive
Fremont, CA 94538

Re: K130656
Trade/Device Name: iFusion
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI, OBO
Dated: June 6, 2013
Received: June 7, 2013

Dear Mr. Jackson:

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,

Kesia Y. Alexander -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

Indications for Use

510(k) Number (if known): K130656

Device Name: iFusion

Indications For Use:

The iFusion connects the iCam (K122572) and iVue (K121739) devices via a sliding bracket mechanism (iShuttle), to facilitate switching between the two devices. The iShuttle provides position adjustment ability of the iCam or iVue device during use.

The iFusion interfaces with the iCam and iVue devices to enable the operation of the iCam and iVue devices from one computer unit.

Prescription Use___X____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K130656_____