



K 122572

JAN 11 2013

Optovue iCam 510(K) Premarket Notification

510(k) Summary

Optovue, Incorporated

iCam Fundus Camera

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

General Information

Manufacturer:

Optovue, Inc.
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Fremont, CA 94538
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Registration No.: 3005950902

Contact Person:

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Optovue, Inc.
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Device Information

Classification:

Class II

Trade Name:

iCam Fundus Camera

Common Name:

Fundus Imaging Device (Camera)

Classification Name:

Ophthalmic Camera, AC-Powered and Accessories (21 CFR § 886.1120)

Predicate Devices

(1) Digital Retinography System (DRS) (K101935)-manufactured by Centervue, SPA.

Intended Use

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.

Indications for Use

Optovue iCam 510(K) Premarket Notification



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.

iCam is indicated for in-vivo viewing of the posterior and external area of the eye and the images are 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

Device Description

The iCam is a non-mydriatic fundus camera for capturing, storing and displaying color fundus images with 1.3 MP @ 12 bits per color channel up to 45 degree (axial arc) field of view. It was designed to provide an acceptable area for broad range, high resolution viewing of most retinal-based and optic nerve pathologies. The design allows for the acquisition of high quality images that are of comparable quality to other predicate ocular cameras. The design incorporates the use of an LED light sources providing two advantages over the flash lamp light source of other cameras: 1) longer life expectancy of the LED compared to the typical Xenon flash lamp, and 2) reliability of solid state devices that allow for more reproducible light characteristics over time.

The LED light source provides lower voltage operation, a higher efficiency overall and allows for smaller design of the system based on the relatively small size of the LEDs compared to the Xenon bulb. LED light source has a considerably longer lifespan than a Xenon light source, while emitting minimal heat compared to the heat generating Xenon source.

The LED light source also relates to reliability of solid state devices that allow for more reproducible image quality over time. Solid state devices that function via an on-or-off state are known to maintain light characteristics such as color temperature, lumens of output, and distribution of light. This characteristic of no demonstrable degradation results in more reproducible images over time.

Safety

There is no change in safety from the iCam's predicate device (K101935) All safety related parameters, such as optical exposure power level, ergonomics, material biocompatibility, and IEC-60601 certification, has been tested and certified by recognized laboratories. The iCam has the same indication and analysis features as previous cleared submission (DRS K101935); and as such, does not raise any safety issues.

Effectiveness

The validation of effectiveness of the iCam has been analyzed in detail and the image quality is similar to the predicate device (DRS K101935). As was indicated in the DRS, the proportion of clinically useful images was tested by comparing the measured data to the predicate device by physicians. The results provided that the iCam is as effective as the predicate device (DRS – K101935)



Substantial Equivalence

The iCam is substantially equivalent to the predicate device with regard to intended use, operating principle, function, material, and energy source. Based on the types of measurements, comparisons made, and validation testing of the effectiveness of the camera, the iCam was found to be substantially equivalent to the predicate device identified previously. The iCam is substantially equivalent to the previously cleared DRS (K101935) device with regards to intended use, operating principle, function, material, and energy source.

Performance Data

Tests:

Software validation tests and side by side comparison tests using the iCam and DRS devices were tested and were found substantially equivalent in image quality and grader agreement.

Clinical Study:

The study was a multi-center, open-label, prospective study evaluating the non-inferiority of the study device, Optovue iCam, relative to the predicate, Centervue DRS with regards to image quality. Photos and clinical study data were collected and data analysis was performed in accordance with documented protocols.

Target enrollment consisted of a total of 120 evaluable subjects from at least 2 sites. Consented subjects underwent an ophthalmic examination and a set of photos collected on the study eye (2 centerfield fundus and 1 external eye) with the study device, iCam, and the predicate device, DRS. The best image of 2 repeat fundus photos was selected for assessment of clinical usefulness by the reviewer, all licensed practitioners in optometry, using a 5-point image quality grading scale. For final analysis, the scale is dichotomized for ease of interpretation at the threshold of image quality grade ≥ 3 that the image is deemed as "clinically useful" or otherwise, and the sample proportion of clinically useful images is considered the primary study endpoint. The non inferiority margin to be utilized in this study was set at 10 percentage points. The non-inferiority margin represents the percentage points below the predicate (DRS) probability of useful images where the study device will be still considered non-inferior. That is, the study device is deemed to be non-inferior to the predicate in light of evidence that the study device is associated with a probability of a clinically useful image which is no worse than 10 percentage points less than that for the predicate. All images are also graded by a second reviewer, also a licensed practitioner in optometry, to assess inter-rater agreement of the 5-point image quality grading scheme utilized by the study.

When images were evaluated by the independent grader, images from the iCam were deemed to be non-inferior compared to those from DRS. Results based on PI grading were similar in terms of non-inferiority. Agreement between PI and independent graders with regards to clinically usefulness of images was concluded to be at an acceptable level in all cases.

In conclusion, it was found that the level of agreement between the iCam and the DRS was high and there was sufficient evidence to determine that the image quality of the iCam is substantially equivalent to that of the DRS.



Test Data

The iCam Fundus Camera has undergone extensive performance testing before release to ensure that the device and its software meet the functional requirements and to demonstrate equivalence to the predicated devices.

A summary of the results of performance testing vs. the device requirements follows:

Performance Item	Requirements	Test Results
Fundus Image	45 degree, 36 bit color image	Yes
Resolution	1.3 Million Pixels at 12 bits per color pixel	Yes
Resolution on retina	≥ 60 line pairs/mm at the center of the field ≥ 40 line pairs/mm at the mid field (r/2) ≥ 25 line pairs/mm at the periphery of the field (r)	Yes Yes Yes
Field of view	45.0 degrees (horizontal)	44.6 degrees
Pixel pitch	10 μm	10.24 μm
Range of focus	-15 D to + 15 D	- 35 D to + 30 D
Minimum pupil size	4.0 mm	4.0 mm
Position of internal fixation targets for central and peripheral fields	CENTRAL: field centered on the foveal pit PERI-NASAL: field centered 5° nasally to the fovea PERI-TEMPORAL: field centered 5° temporally to the fovea NASAL: field centered 15° nasally to the fovea TEMPORAL: field centered 15° temporally to the fovea SUPERIOR: field centered 15° superiorly to the fovea INFERIOR: field centered 15° inferiorly to the fovea	Actual position (for normally fixating subjects) within ± 1° from expected position
Alignment	Manual alignment using split-image technique	Yes

Conclusion

We have established an acceptable agreement in image quality review of photos acquired by iCam and DRS devices. The sample proportion of clinically useful images are similar to both devices, hence the iCam is substantially equivalent to the predicate device.

As described in this 510(k) Summary, all testing and analyses were completed on the iCam to ensure that substantial equivalence with the identified predicate device has been demonstrated.



January 11, 2013

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

Optovue, Inc.
Ms. Azimun Jamal
Director of Regulatory Affairs
2800 Bayview Drive
Fremont, CA 94538

Re: K122572
Trade/Device Name: iCam Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: AC-Powered Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: November 14, 2012
Received: November 15, 2012

Dear Ms. Jamal:

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,

Kesia Y. Alexander

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



Statement of Indications for Use

510(k) Number (if known): K122572

Device Name: iCam Fundus Camera

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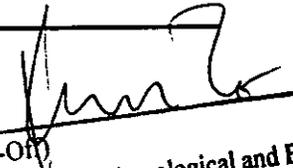
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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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