JUN 1 6 2009

510(k) SUMMARY

Imedos GmbH's Static Vessel Analyzer

510(k) Number: K082196

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 12, 2009

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Trade/Device Name: Static Vessel Analyzer (SVA)
Classification Name: Opthalmic camera
Regulation Number: 21 CFR 886.1120
Product Code: HKI, Class II

Classification Name: Medical image communications device.
Regulation Number: 21 CFR 892.2010
Product Code: NFF, Class I 510(k) exempt

Classification Name: Medical image storage device
Regulation Number: 21 CFR 892.2020
Product Code: NFG, Class I 510(k) exempt

Indications for Use:

Static Vessel Analyzer (SVA) with VesselMap2 is intended to capture, display, store, and manipulate images of the eye, especially the retina area, as well as surrounding areas, to aid in diagnosing or monitoring diseases of the eye that may be observed and photographed. Specifically, the VesselMap2 software is intended to be used for semiautomated measurement and calculation of the retinal artery/vein diameter ratio.

Technological Characteristics:

The IMEDOS SVA unit is designed as a complete Fundus Imaging system or the software can be sold separately as a standalone product. The SVA software consist of two components – VisualIS, an imaging software for capture, display, storage and manipulation of images of the eye and VesselMap2, an add-on for enhanced analysis of retina images.

VisualIS captures the images which are provided by the fundus camera and the connected digital image sensor. Together with an image set the data of the patient are recorded and stored. The complete examination can be stored and opened for follow-up examination purposes.

The add-on VesselMap2 offers a semi-automated measurement for Arterial – Venous Ratio of retinal vessels. The software allows the user to select veins and arteries. Vessel diameters are estimated by the software and the ratio of the analyzed arteries to veins is calculated. The image is not altered in any way during this calculation.

The manual and semi-automatic calculation were compared and verified on representative retina images and the results show improved repeatability of the semi-automated calculations based on the uncertainty and precision of manual vessel diameter determination based on the user's subjective perception of vessel edges.

Performance Data

Imedos completed a comprehensive method comparison study assessing the VesselMap software function compared to an accepted, manual method for determining arterial-venous ratios. This study assessed agreement, reproducibility, and repeatability. The completed study demonstrated:

1. Agreement between manual and semi-automatic (VesselMap2) retinal vessel analysis, without any indication of statistically significant differences between methods;
2. Smaller intragrader variability (repeatability) and intergrader variability (reproducibility) for the semi-automatic method (VesselMap2) than for the manual method;
3. In the manual method, a systematic bias between the two graders exists, which is not the case in the semi-automatic method. Thus, the comparison study demonstrated that the VesselMap software does not introduce reader-to-reader bias;
4. Appropriate intravisit and intervisit reproducibility for the semi-automatic method. The visit-to-visit variability (whether for manual or semi-automated analysis) was shown to be much higher than the variability in results associated with the device.

Substantial Equivalence

The Imedos SVA System has the same intended use, principles of operation and technological characteristics as the Carl Zeiss FF450plus VISUPAC System (K011877). The minor differences between the Carl Zeiss FF450plus VISUPAC System and the Imedos SVA system do not raise new questions of safety or effectiveness. Performance data demonstrate that the SVA System is as safe and effective its predicates. Thus, the SVA System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Imedos GmbH
c/o Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

JUN 16 2009

Re: K082196
Trade Name: Static Vessel Analyzer (SVA)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI, NFF, NFG
Dated: May 22, 2009
Received: May 26, 2009

Dear Mr. Kahan:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Tessia Alexander for

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

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Prescription Use ___X_____ AND/OR Over-The-Counter Use _____

(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 and Ear,
Nose and Throat Devices

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