

AUG - 5 1998

Appendix D

510(K) SUMMARY
ODYSSEY OPTICAL SYSTEMS S²LO

This 510(K) summary of safety and effectiveness for the scanning laser ophthalmoscope is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(K) summary.

Applicant: Odyssey Optical Systems, LLC

Address: 30-31 Union Wharf
Boston, MA 02109

Contact Person: Greg Heacock, Ph.D.
Vice President

Telephone: 617-720-5254
617-720-5260 (fax)

Preparation Date: May, 1998
(of the Summary)

Device Name: Odyssey Optical Systems S²LO

Common Name: Ophthalmoscope

Classification: Class II

Name: (see: 21 CFR 886.1570). Product Code: HLI. Panel: 86.

Legally marketed
predicate

device: Rodenstock Scanning Laser Ophthalmoscope and Humphrey Optical
Coherence Tomography Scanner

Description

of the Device: The S²LO is a medical imaging device utilizing three Class I lasers of different wavelengths (532 nm, 670 nm and 810 nm). Illumination from these lasers can be used independently or collectively to diagnose and monitor diseases and disorders of the posterior pole of the eye. The device operates on a 12 volt power supply and produces 0.8 mW/cm² of retinal illumination.

The non-invasive, non-contact S²LO allows imaging of the posterior segment of the human eye. High resolution images of the posterior segment of the eye can be captured, printed, stored electronically or transmitted for referral purposes.

Indications for

Use: The S²LO is indicated for diagnosing and monitoring diseases and disorders that manifest themselves in the posterior pole of the eye.

Comparison to: The specifications of the Odyssey Optical Systems S²LO are the same or very similar to those of the claimed predicates.

Performance Data: None. The specifications and indications for use of the Odyssey Optical Systems S²LO are the same or very similar to those of the claimed predicate devices. The Odyssey Optical Systems S²LO has the same indications for use for which the claimed predicates have been cleared and has no additional indications for use.

Because of this, performance data were not required.

Conclusion: Based on the foregoing, Odyssey Optical believes that the S²LO is substantially equivalent to legally marketed predicate devices.



MAY 29 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Odyssey Optical Systems, LLC
c/o Ms. Maureen A. O'Connell
2710 Oakbrook Lane
Weston, FL 33332

Re: K981640
Trade/Device Name: S²LO Scanning Laser Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: July 27, 1998
Received: July 27, 1998

Dear Ms. O'Connell:

This letter updates our substantially equivalent letter of August 5, 1998.

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 (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

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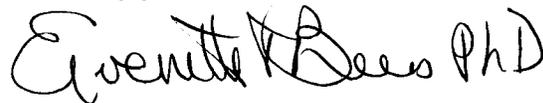
device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html>

Sincerely yours,



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

510(K) Number (if known): K981640

Device Name: Odyssey Optical Systems S²LO

Indications For Use:

The Odyssey Optical Systems S²LO is indicated for diagnosing and monitoring diseases and disorders that manifest themselves in the posterior pole of the eye.

Evelyn T. Beers
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981640

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use
(Per 21 CFR 810.109)

Over-The-Counter Use