K080460

OPKO/OTI INSTRUMENTATION
A Division of OPKO Health, Inc.

NOV 14 2008

510(k) Summary
October 1, 2008

1. Submitter Information

Name: OPKO Instrumentation/OTI
4400 Biscayne Boulevard
Miami, FL 33137

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Contact Person: Jane Hsiao
e-mail: jhsiao@opko.com

Date Submitted: October 1, 2008

2. Name of Device

Trade Name: Spectral OCT/SLO
Common Name: Ophthalmoscope using optical coherence tomography
Classification Name: Ophthalmoscope, a-c powered, 890HLI

3. Equivalent legally marketed devices.

K042885 OCT Ophthalmoscope, Ophthalmic Technologies, Inc
K033123 Stratus OCT, Carl Zeiss Meditec System

4. Description

The OPKO/OTI Spectral OCT/SLO is a computerized instrument that employs non-invasive, low-coherence interferometry to acquire simultaneous high-resolution cross-sectional OCT (Optical Coherence Tomography) and confocal images of ocular structure, including retina, retinal nerve fiber layer, macula and optic disc of the eye.

5. Indication for Use:

The Spectral OCT/SLO is a non-contact, high-resolution non-invasive tomographic and confocal imaging device. It is indicated for in vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of posterior ocular structures including: retina, macula, retina nerve fibre layer and optic disk. It is used as a diagnostic device to aid in the detection and management of ocular diseases affecting the posterior segment of the eye. In addition, cornea, sclera and conjunctiva can be imaged with the system by changing the focal position.

6. Technological Characteristics:

The OPKO/OTI Spectral OCT/SLO and the predicate device, Zeiss Stratus OCT both utilize Optical Coherence Tomography, which relies upon interferometry of superluminescent diode light, reflected from the fundus of the eye, to produce cross-sectional image of the retina. Both systems have similar hardware system consist of an optical system, the light source, a power supply and a computer with software for data analysis and image processing. The two systems differ in the that OPKO/OTI Spectral OCT/SLO uses spectrometer with optical grading and linear CCD camera while Stratus OCT uses photo-detector to detect the return OCT light signal from the eye.

7. Performance Data

a. Non-clinical tests

The Spectral OCT/SLO has had accuracy test, optical emissions analyses, image comparison, electrical safety test, electromagnetic compatibility test and software validation tests.

b. Clinical tests:

Thirty six subjects, including normal and patients with retinal or glaucoma pathologies, participated in a controlled prospective comparative study to evaluate the performance (precision and agreement) of Spectral OCT/SLO and the predicate device Stratus OCT in the measurement of retinal, RNFL thickness and optical nerve disc ratio.

c. Conclusions

The Spectral OCT/SLO is equivalent or better in the precision tests when compares to the predicate device. The regression analysis between the measurements are substantially equivalent between the test and the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OPKO Health, Inc.
c/o Jane Hsiao, Ph.D.
OPKO Health, Inc.
4400 Biscayne Blvd.
Miami, Florida 33137

NOV 14 2008

Re: K080460
Trade/Device Name: Spectral OCT/SLO
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: November 11, 2008
Received: November 12, 2008

Dear Dr. Hsiao:

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 such 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); 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 begin 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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: K080460
Device Name: Spectral OCT/SLO

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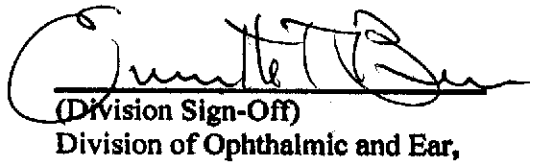
Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 and Ear, Nose and Throat Devices

510(k) Number _____