K111628

Special 510k Summary

AUG 19 2011

Name of Device	P200T Ophthalmoscope
Common or Usual Name	Scanning laser ophthalmoscope
Classification Name	Scanning laser ophthalmoscope (21 C.F.R. § 866.1570)
Product Code	MYC
Submitter	Optos plc, Queensferry House, Carnegie Business Campus Dunfermline, Fife, KY11 8GR United Kingdom Phone: 011 44 1383 843300 Facsimile: 011 44 1383 843333
Contact Person:	Robert Tweedlie, Ph.D.
Date Prepared	July 21, 2011
Predicate Device	Optos Limited's Panoramic 200CAF (K100644)

Indications for Use

The P200T scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Principles of Operation and Technological Characteristics

The Optos P200T is a scanning laser ophthalmoscope that uses lasers as a light source that is scanned by a deflection system in two axes across the retina to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture in a computer and displayed either on a cathode ray tube or a liquid crystal display.

Summary of Modifications to the Predicate Device

- The scanhead used for image capture is in a different enclosure and is a table top model;
- There is no head and chin rest, but there are external handgrips to help patient positioning;
- There is no powered table which attaches onto the scanhead; rather, there is an electronic enclosure that connects to the scanhead;
- The mirror used for the horizontal scan is directly connected to a motor, whereas the horizontal scan mirror in the predicate device is motor driven via a drive belt;
- An optional touch screen monitor is used, rather than a monitor, keyboard, and mouse;
- Combined laser power monitoring and a single exposure shutter are used, rather than individual laser power monitoring and individual shutters for each wavelength channel;

- The return path does not have a translation stage to move optical elements in and out of this path;
- The autofluorescence sensor has been replaced with a new sensor with greater sensitivity; and
- The Laser Radiation Management (LRM) firmware and capture software have minor changes consistent with the modifications described above.

Table of Modifications

Sub-category	P200CAF	P200T
Imaging Modes	• Imaging modes are the same • Autofluorescence is effected by laser select shutter being closed and return path has optical elements removed using a translation stage for autofluorescence. • Belt drive for horizontal slow scan mirror • Translation stage moves optical elements out of return path for autofluorescence mode	• Imaging modes are the same • Autofluorescence is effected by switching off red laser and return path has fixed optical elements • Direct drive for horizontal slow scan mirror • Detector gain change for autofluorescence; no translation stage
User Interface	• Scan head rests on a supporting, powered table • Scan head has integrated monitor • Remote review/storage PC • User interface: - Monitor, keyboard and mouse - Handheld patient capture button - Handheld table up/down button	• Scan head rests on a supporting table • Scanhead has integrated monitor • Remote review/storage PC • User interface: - Monitor, keyboard and mouse - Touchscreen optional - Handheld patient capture button
Patient alignment system (PAS)	• Same for both devices	• Same for both devices
Laser Radiation Management (Including safety software)	• Individual laser power monitoring • Individual laser shutters and separate exposure shutter • Vertical and horizontal scan status monitoring • All lasers disable on failure • Shutter closure on failure • System lock-out on failure • Exposure timing monitor • Exposure rate control • Dual redundancy	• Combined laser power monitoring • Single exposure shutter • Vertical and horizontal scan status monitoring • R/G disable on failure • Shutter closure on failure • System lock-out on failure • Exposure timing monitor • Exposure rate control • Dual redundancy
System configuration	• Scanhead attached to a powered table	• Scanhead connected by cable to an electronic subsystem
Patient support	• Head rest/Chin support • Face pad	• Face pad and handgrips

Substantial Equivalence

The Panoramic 200T has the same intended use and indications for use and similar principles of operation and technological characteristics as the predicate device. The minor technological differences between the Panoramic 200T and the predicate device do not raise any new questions of safety and effectiveness. Thus, the Optos Panoramic 200T Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscope (SLO), the P200CAF (K100644).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Partner
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Columbia Square
555 Thirteenth Street, NW
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AUG 19 2011

Re: K111628
Trade Name: Optos Panoramic 200T Scanning Laser Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulation Class: Class II
Product Code: MYC
Dated: July 21, 2011
Received: July 21, 2011

Dear Mr. Holstein:

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,

Tesia 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

Statement for Indication for Use

510(k) Number (if known): K111628

Device Name: Optos Panoramic 200T Scanning Laser Ophthalmoscope

Indications for Use:

The Panoramic 200T scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Prescription Use _✓____ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(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

510(k) Number K111628