K100644

510k Summary-Optos Panoramic 200CAF

Name of Device	Panoramic 200CAF Ophthalmoscope
Common or Usual Name	Scanning laser ophthalmoscope
Classification Name	Ophthalmoscope (per 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	June 14, 2010
Predicate Device	Optos Limited's Panoramic 200 (K983999)

JUL 16 2010

Indications for Use

The Panoramic 200CAF 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.

Technological Characteristics

The Panoramic 200CAF is a conventional scanning laser ophthalmoscope (SLO), which uses a low power laser beam to scan in two dimensions over the retina. The reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

The wavelengths of the lasers residing in the Optos Panoramic 200CAF and the P200 are the same. The generation of the image is performed in the conventional manner using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage. The scanning of the beams on the two axes is done using a conventional rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan. An alignment pattern helps ensure that the patient's eye is correctly positioned.

The reflected energy from the retinal surface is passed back through the device to an array of two discrete detectors (effectively a red and a green channel). For the Panoramic 200CAF and the P200, in standard imaging mode, the images produced can be viewed either as a composite image (red and green images combined) or separate as a green channel and a red channel image. The Panoramic 200CAF can also generate an alternate red channel image that shows the natural fluorescence (autofluorescence) of the eye. In this imaging mode, the retina is illuminated using the green laser, while the red laser optical path is blocked by a shutter. In this imaging mode, the red channel image now displays the naturally occurring fluorescent material of the retina, such as lipofuscin. The signal strength varies as the laser beam is scanned across the eye, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.

This scanning function is housed in the 'scanhead', which is seated on a table that can move up and down and this affords a height adjustment to achieve correct patient positioning.

The Panoramic 200CAF and P200 capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, the Panoramic 200CAF and Panoramic 200 display a series of thumbnail sketches in the order in which they were scanned. The Panoramic 200CAF, like the P200, allows the user to view one or more images of the eye.

Principles of Operation:

Both the P200CAF and the P200 have very similar principles of operation. Both devices use 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.

Both the P200CAF and the P200 use the same red and green lasers. Both devices can generate a composite red/green image. The autofluorescence imaging mode present in the P200CAF can be used by the healthcare professional in conjunction with the standard composite (red/green) and the associated separated red and green channel images to aid in the diagnosing and monitoring of diseases and disorders that manifest themselves in the eye.

The mechanism for autofluorescence is well understood and documented. The green wavelength is primarily reflected by the retinal pigment epithelium (RPE)/photoreceptor interface and the red light is reflected by the choroid. Autofluorescence looks at the distribution of lipofuscin within the RPE. Thus, autofluorescence gives an alternate view of the retinal layers and is complimentary to the red/green composite reflectance image and the separated red and green reflectance images.

Performance Testing:

Compliance to electrical safety (including EMC), light emitting products, programmable devices and biocompatibility standards are met. Each device is tested for electrical safety, laser power output and correct functioning of the laser radiation management system against set criteria and limits. Additionally, performance testing was conducted to demonstrate that

the P200CAF accurately and reproducibly produces images the eye in both standard and autofluorescence imaging modes.

Substantial Equivalence

The Panoramic 200CAF has the same intended use, similar principles of operation, and similar technological characteristics as the predicate device. The minor differences between the Panoramic 200CAF and the predicate device do not raise any new questions of safety and effectiveness. Thus, the Optos Panoramic 200CAF Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscopes (SLO), the P200 (K983999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 15 2010

Re: K100644
Trade Name: Panoramic 200CAF
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulation Class: Class II
Product Code: MYC
Dated: June 15, 2010
Received: June 15, 2010

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,

Keona 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): K100644

Device Name: Optos Panoramic 200CAF Scanning Laser Ophthalmoscope

Indications for Use:

The Panoramic 200CAF 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 K100644