K102492

Special 510k Summary-Optos P200MAAF

SEP 30 2010

Name of Device	P200MAAF Ophthalmoscope
Common or Usual Name	Scanning laser ophthalmoscope
Classification Name	Scanning laser ophthalmoscope (per 21 C.F.R. § 866.1570)
Product Code	MYC (Class II)
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	August 31st, 2010
Predicate Device	Optos Limited's Panoramic 200MA (K060424) and Optos Limited's Panoramic 200CAF (K100644)

Indications for Use

The P200MAAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Technological Characteristics

The P200MAAF 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 blue, red and green lasers and their corresponding wavelengths are the same in the Optos P200MAAF and the P200MA. The other predicate, the P200CAF does not have the blue laser as it does not have an angiographic mode but it does have the exact same red and green lasers in terms of type and wavelength.

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 P200MAAF, P200MA, and the P200CAF, 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 P200MAAF and P200CAF 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.

The Panoramic P200MAAF and the P200MA also have an angiographic mode where the red and green lasers are blocked and only the blue laser illuminates the retina. The blue laser causes the fluorescence of an injected contrast media (or dye), fluorescein. Fluorescein absorbs in the blue and emits in the green part of the visible spectrum. In this imaging mode, the green channel now displays the flow (and possible leakage) of the dye through the blood vessels of the eye.

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 P200MAAF, P200MA, and P200CAF capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, all three devices display a series of thumbnail sketches in the order in which they were scanned. The P200MAAF, like the P200MA and P200CAF, allows the user to view one or more images of the eye.

Principles of Operation:

The P200MAAF, P200MA, and the P200CAF have very similar principles of operation. Each device 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.

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.

Substantial Equivalence

The P200MAAF has no new intended use, similar principles of operation, and similar technological characteristics as the predicate devices, the P200MA and the P200CAF. The minor differences between the P200MAAF and the predicate devices do not raise any new

questions of safety and effectiveness. Thus, the Optos P200MAAF Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscopes (SLO), the P200MA (K060424) and the P200CAF (K100644).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 30 2010

Re: K102492
Trade Name: Panoramic 200MAAF
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulation Class: Class II
Product Code: MYC
Dated: August 31, 2010
Received: August 31, 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

(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,

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

K102492

SEP 30 2010

510(k) Number (if known): K102492

Device Name: Optos P200MAAF Scanning Laser Ophthalmoscope

Indications for Use:

The P200MAAF scanning laser ophthalmoscope is indicated for use as a wide field and retinal fluorescence and 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)

9/30/2010

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K102492