

FEB 3 1999

K 983999

2 510(k) Summary

Optos Panoramic200

Name of Device Panoramic200 Ophthalmoscope

Common or Usual Name Scanning Laser Ophthalmoscope (SLO)

Classification Name Ophthalmoscope, AC powered
(per 21 C.F.R. 866.1570)

Product Code HLI

Submitter Optos plc
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Dunfermline,
Fife,
Scotland
United Kingdom

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Contact Person: Mr. Philip Rickett

Date Prepared: 1 November 1998

Predicate Devices

<u>Trade name</u>	<u>Manufacturer</u>	<u>510(k)</u>
S ² LO	Odyssey Optical Systems	K981640
Scanning Laser Ophthalmoscope (SLO)	Rodenstock	K882517
Scanning Laser Ophthalmoscope (SLO)	Rodenstock	K871268

Intended Uses

Optos plc's ("Optos") Panoramic200 and Odyssey Optical System's S²LO ("the Odyssey S²LO") and G. Rodenstock Instruments GmbH Scanning Laser Ophthalmoscopes ("the Rodenstock SLOs") is intended to examine the retina of the eye. The Panoramic200 and the Odyssey S²LO, and the Rodenstock SLOs are indicated for diagnosing and monitoring disease

and disorders that manifest themselves in the posterior pole of the eye. Thus, the Panoramic200 Ophthalmoscope has the same intended use and the same indications as these predicate devices.

Principles of Operation and Technological Characteristics

The Optos' Panoramic200 and the predicate devices are Scanning Laser Ophthalmoscopes (SLO) that work by the same method. They use a laser or lasers as a light source that is scanned by a deflection system in two axes across the retina of the eye to generate a color 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 either in a personal computer and displayed either on a cathode ray tube or an liquid crystal display.

The technological differences between the Panoramic200 Ophthalmoscope and its predicate devices are the Panoramic200's lack of an infrared laser, the size and shape of the Panoramic200's deflection system, and the Panoramic200's different display format, wider imaging angle, higher resolution, and use of an eye piece. However, these differences do not raise any new questions of safety or effectiveness

Performance Standards

The Optos Panoramic200 Ophthalmoscope is a Class I laser device. This device complies with 21 C.F.R., Parts 1010 and 1040.

The Optos Panoramic200 Ophthalmoscope complies with the following standards:

BS EN 60601-1:1993	Medical electrical equipment. General requirements for safety;
BS EN 60601-1-1:1993	Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems;
BS EN 60601-1-2:1993	Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility;

BS EN 60601-1-4:1997	Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for programmable electrical medical systems.
BS EN 60825-1:1994 AMD2 UL2601:1994	Safety of laser products. Part 1. Equipment classification, requirements and user's guide. Medical electrical equipment. General requirements for safety.
CAN/CSA-C22.2 No.601.1-M90 AS 3200.1:1990/ NZ 6150:1990 JIST 1001/1002:1992	Medical electrical equipment. General requirements for safety.

Conclusion

The Panoramic200 has the same intended use, the same indications and very similar principles of operation and technological characteristics as the Odyssey S²LO and the Rodenstock SLOs. The minor differences between the Panoramic200 and the predicate devices do not raise any new questions of safety or effectiveness. Thus, the Optos Panoramic200 Ophthalmoscope is substantially equivalent to legally marketed Scanning Laser Ophthalmoscopes (SLO).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optos PLC
c/o Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K983999
Trade Name: Panoramic200 Ophthalmoscope
Regulatory Class: II
Product Code: 86 HLI
Dated: November 9, 1998
Received: November 9, 1998

Dear Mr. Holstein:

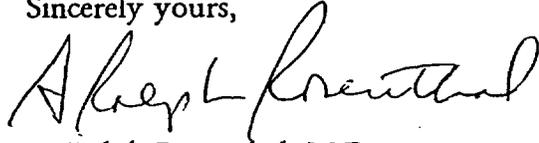
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983999

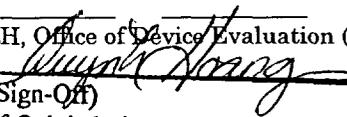
Device Name: Optos Panoramic200 Scanning Laser Ophthalmoscope

Indications for Use:

This device is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

(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 Devices

510(k) Number K983999

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)