SEP 2 1 2005

K050807

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: OphthalMed LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (678) 623- 3765
5-Contact Person: Jay Mansour
6-Date summary prepared: July 14th, 2005
7-Device Trade or Proprietary Name: 20g SMA Laser/Illumination/Aspiration/Back-wash probes, Model LF100
8-Device Common or usual name: **(1)** Ophthalmic laser, (2) Endoillumination probe and (3) vitreous aspiration
9-Device Classification Name: (1) Ophthalmic laser, (2) Light, surgical, fiberoptic and (3) Instrument, vitrous aspiration and cutting
10-Substantial Equivalency is claimed against the following device:
20g and 25g SMA Laser Fibers, Model LF20 and LF25 from OPHTHALMED LLC (510k #K021696), as well as 510k #K982462 and K946135.

11-Description of the Device:

This device consists of the following parts already connected to each other:
- Handpiece with a 20G extension that holds the tip of the fibers and tubes, and guides it inside the eye.
- 8 ft fiber.
- A special connector that attaches the laser fiberoptic end to the laser source.
- A special connector that attaches the illumination fiberoptic end to the illumination source
- Luer lock that attaches the aspiration/ back-wash tube to the vitrectomy machine
- A flexible plastic jacket covers the length of the fiberoptics and tubes.

Laser fiberoptic provides the function of laser photocoagulation treatment. Illumination fiberoptic (by providing illumination) provides the physician with the view at the surgical site, while aspiration/back-wash tube allows suction of intraocular fluids at the surgical site to facilitate the laser photocoagulation.

12-Intended use of the device:

For use to perform endo-ocular laser photocoagulation treatments, with illumination, aspiration and back-wash during surgical interventions. The operating wavelength is 500 nm to 1,100 nm

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution.

FDA file reference number	510k #K021696 for laser	510k #K982462 for illumination	510k #K946135 for aspiration/back-wash
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**	**Comparison result**	**Comparison result**
Indications for use	Identical	Identical	Identical
Target population	Identical	Identical	Identical
Design	Similar	Similar	Similar
Materials	Similar	Similar	Similar
Performance	Similar	Similar	Similar
Sterility	Similar (Ethylene Oxide)	Similar (Ethylene Oxide)	Similar (Ethylene Oxide)
Biocompatibility	Similar	Identical	Identical
Mechanical safety	Similar	Similar	Similar
Chemical safety	Similar	Similar	Similar
Anatomical sites	Identical	Identical	Identical
Human factors	Identical	Identical	Identical
Energy used and/or delivered	Identical	Similar	Similar
Compatibility with environment and other devices	Identical	Identical	Identical
Where used	Identical	Identical	Identical
Standards met	Identical	Identical	Identical
Electrical safety	Identical (not applicable)	Identical (not applicable)	Identical (not applicable)
Thermal safety	Identical (not applicable)	Identical (not applicable)	Identical (not applicable)
Radiation safety	Identical (not applicable)	Identical (not applicable)	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

OphthalMed LLC
c/o Mr. Jay Mansour
Director, QA and Regulatory Affairs
1308 Morningside Park Dr.
Alpharetta, GA 30022

Re: K050807
Trade/Device Name: OphthalMed 20G SMA Laser/Illumination/Aspiration/ Back-wash probe, Model LF100
Regulation Number: 21 CFR 886.4390
Regulation: Ophthalmic laser
Regulatory Class: II
Product Code: HQF
Dated: August 31, 2005
Received: September 1, 2005

Dear Mr. Mansour:

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.

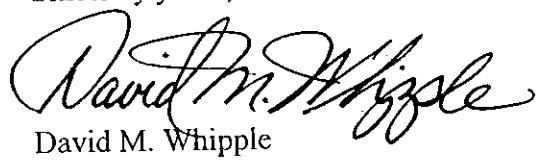
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David M. Whipple
Acting 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 (if known): K050807

Device Name: Laser/Illumination/Aspiration/Back-wash probe, LF100

Indications For Use:

For use to perform endo-ocular laser photocoaguation treatments, with illumination, aspiration and back-wash during surgical interventions. The operating wavelength is 500nm to 1,100nm.

Prescription Use ✔ 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 Ear,
Nose and Throat Devises

510(k) Number K050807