K031023
1 of 2

Peregrine Surgical Ltd.
51 Britain Drive
ew Britain, PA 18901

JUN 27 2003

March 17, 2003

Premarket Notification [510(k)] Summary

Submitter: Peregrine Surgical Ltd.
51 Britain Drive
New Britain, PA 18901
Phone: (215) 348-0456
Fax: (215) 348-5526

Official Correspondent: Jayne Guthrie

Trade Name: Peregrine Illuminated Laser Probe

Common Name: Ophthalmic Laser Probe

Registration Number: 2529392

Classification: Class II

Class Name: We were unable to find the device listed in the Disposable classification regulations, 21 CFR Parts 862-892 [807.87 (c)]

Panel: Ophthalmic

Product Code: HQF

Device Description: The Peregrine Illuminated Laser Probe is an ophthalmic laser delivery device. By its design, it does not generate, intensify or significantly reduce energy. It consists of a connector that is plugged into an existing laser source, a glass fiber for laser delivery and acrylic fiber for illumination with PVC jacket, a Delrin handpiece and 304 stainless needle. The specific laser source to which the probe is connected will be specified in the "Indications for Use."

Statement of indications for use. - For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip

EL: 215-348-0456
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Substantial Equivalence Comparison

Substantial Equivalence to: Product PD600.00 K024061 Peregrine Straight Laser Probe	**Substantial Equivalence to: HGM Illuminating Laser Probe 510K K931784 Manufactured by Gamp & Assoc.**	**Application for 510K Peregrine Illuminated Laser Probe Manufactured by Peregrine**
Light transmission for photocoagulation	Illumination and Light transmission for photocoagulation	Illumination and Light transmission for photocoagulation
Aluminum connector	Aluminum connector	Delrin connector
Delrin Handpiece	Delrin Handpiece	Delrin Handpiece
Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core 400 micron
PVC Jacket	Teflon Jacket	Teflon Jacket
Length 101 inches	Length 96 inches	Length 81 inches
304 Stainless Needle	304 Stainless Needle	304 Stainless Needle
20 Gauge	20 Gauge	25 Gauge
Max power output 1 watt	Max power output 1 watt	
No illumination	Illumination	Illumination
	Acrylic Optical fiber	Acrylic Optical fiber
	Aluminum illumination fiber connector	Aluminum illumination fiber connector

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2003

Mr. Todd Richmond
Director of Product Development
Peregrine Surgical Ltd.
51 Britain Drive
New Britain, Pennsylvania 18901

Re: K031023
Trade/Device Name: Peregrine Illuminated Laser Probe
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF
Dated:
Received:

Dear Mr. Richmond:

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) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510K Number (if known):

Device Name: Peregrine Illuminated Laser Probe

Indications for Use:

For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____xx_____ OR Over-The-Counter Use_____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031023