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

JUN 21 2006

K061024

March 21, 2006

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 Soft Tip Aspirating Laser Probe

Common Name: Ophthalmic Aspirating Laser Probe

Registration Number: 2529392

Classification: Class II (Primary) **Class II (Secondary)**

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 (Primary) HQE (Secondary)

Regulation Number:	21 CFR 886.4390 (Primary)	21 CFR 886.4150 (Secondary)
Regulation Name:	Ophthalmic Laser (Primary)	Vitreous aspiration and cutting instrument. (Secondary)

Device Description: The Peregrine Soft Tip Aspirating Laser Probe is an ophthalmic laser delivery device with aspirating capability. It consists of a connector that gets plugged into the Coherent/Alcon laser, a silicone aspirating line with female luer which attaches to an aspiration line associated with the operating system, a glass fiber with PVC jacket, a silicone reflux boot, a Delrin handpiece, a 304 stainless needle and silicone sleeve (soft tip) attached to the distal tip of the 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 use during ophthalmic surgery for photocoagulation and aspiration in conjunction with Coherent/Alcon laser and aspiration units. Laser wavelengths range from 193nm to 633nm.

Substantial Equivalence Comparison

Application for 510K Product PD720.60 Peregrine Soft Tip Aspirating Laser Probe	**Substantial Equivalence to: Aspirating Laser Probe 510K K954308 Manufactured by Gamp & Assoc.**	**Substantial Equivalence to: Infinitech Aspirating Laser Probe 510K K946135 Manufactured by Infinitech**
Light transmission for photocoagulation	Light transmission for photocoagulation	Light transmission for photocoagulation
905 SMA laser connector	905 SMA laser connector	905 SMA laser 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 .008" (200 microns)
Silicone aspirating line	Silicone aspirating line	Silicone aspirating line
Female connector	Female connector	Female connector
Silicone Reflux Boot	Silicone Reflux Boot	Silicone Reflux Boot
Silicone Soft Tip	Silicone Soft Tip	Silicone Soft Tip
PVC Jacket	PVC Jacket	PVC Jacket
Length 101 inches	Length 96 inches	Length 96 inches
304 Stainless Needle	304 Stainless Needle	304 Stainless Needle
20 Gauge	20 Gauge	20 Gauge
Max power output 1 watt	Max power output 1 watt	Max power output 1 watt

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 21 2006

Peregrine Surgical Ltd.
c/o Theodore Richmond, Director of Product Development
51 Britain Dr.
New Britain, PA 18901

Re: K061024
Trade/Device Name: Peregrine Soft Tip Aspirating Laser Probe, Model PD720.60
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF and HQE
Dated: June 1, 2006
Received: June 5, 2006

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510K Number (if known):

Device Name: Peregrine Soft Tip Aspirating Laser Probe

Indications for Use:

For use during ophthalmic surgery for photocoagulation and aspiration in conjunction with Coherent/Alcon laser and aspiration units. Laser wavelengths range from 193nm to 633nm.

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_____

6/19/2006

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

510(k) Number K061024