K980027

March 23, 1998

Premarket Notification [510(k)] Summary

MAR 31 1998

Submitter: Peregrine Surgical Ltd.
4050D Skyron Drive
Doylestown, PA 18901
Phone: (215) 348-0456
Fax: (215) 348-5526

Official Correspondent: Amy Hessenthaler

Trade Name: Peregrine Shielded Diffusion Probe

Common Name: Fiber Optic Light Pipe with wide angle dispersion of illuminated field

Registration Number: 2529392

Classification: Class II

Class Name: Not Known

Panel: Ophthalmic

Product Code: MPA

Device Description: The Peregrine Shielded Diffusion Probe is a single use light guide approximately 6' in length consisting of the following: A Universal Aluminum connector at the proximal end to fit into a surgical light source. A polyethylene jacket through which an Acrylic fiber runs. A Delrin Handpiece with a 20 GA Stainless Steel Needle at the distal end. The acrylic fiber, which is polished and affixed at both ends, is tapered and extends past the tip to achieve the diffusion of light. The Stainless Steel Needle is ground at an angle so as to "shield" a portion of the exposed fiber in order to reduce light emitted in the direction of the surgeon's eyes. (glare)

Statement of Indications for use. - For Illumination, coagulation, irrigation/aspiration, and tissue manipulation during ophthalmic surgery.

Substantial Equivalence Comparison

Peregrine **Peregrine Shielded Diffusion Probe** **Application for 510(K)**	**Peregrine** **Peregrine Diffusion Light Pipe** **Manufactured for Grieshaber**	**Peregrine** **Peregrine Wide Angle Light Pipe** **Manufactured for Storz**
Wide Angle Light Diffusion	Wide Angle Light Diffusion	Wide Angle Light Diffusion
Delrin Handpiece	Delrin Handpiece	Delrin Handpiece
20 GA Stainless Steel Needle	20 GA Stainless Steel Needle	20 GA Stainless Steel Needle
Polyethylene Jacket	Polyethylene Jacket	Teflon Jacket
Acrylic Fiber w/Tapered End	Acrylic Fiber w/ Prism Wafer	Acrylic Fiber w/ Sapphire Ball
Aluminum Connector	Aluminum Connector	Acetal Connector
Single Use	Single Use	Single Use

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

MAR 3 1 1998

Mr. Todd Richmond
Peregrine Surgical Ltd.
Contract Manufacturer
4050D Skyron Drive
Doylestown, PA 18901

Re: K980027
Trade Name: Peregrine Shielded Diffusion Probe
Regulatory Class: II
Product Code: 86 MPA
Dated: December 30, 1997
Received: January 5, 1998

Dear Mr. Richmond:

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 (Premarket 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

510K Number (if known):

Device Name: Peregrine Shielded Diffusion Probe

Indications for Use:

For wide angle illumination of the posterior segment during ophthalmic surgery

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_____

Marsha L. Burke Nicholas

(Division Sign-Off)
Division of Ophthalmic Devices
(510(k) Number K980027