K980530

Peregrine Surgical Ltd.
4050D Skyron Drive
Doylestown, PA 18901

MAY 12 1998

May 11, 1998

Premarket Notification [510(k)] Summary

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 Fiber Optic Bipolar Straight Pick
Peregrine Fiber Optic Bipolar Angled Pick

Common Name: Fiber Optic Light Pipe with Pick and Coagulation

Registration Number: 2529392

Classification: Class II

Class Name: Not Known

Panel: Ophthalmic

Product Code: 86 MPA, 21 CFR 876.1500

Device Description: The Peregrine Fiber Optic Bipolar Straight and Angled Picks are fiberoptic illuminators with capabilities to manipulate tissue and coagulate blood. They consist of the following: A connector at the proximal end to fit into a surgical light source. A polyethylene jacket through which an Acrylic Fiber and fine insulated electrical wires run. A Delrin handpiece with a 20 GA stainless steel needle at the distal end. An insulated inner blunt needle running parallel to the outer blunt needle with a gap of approximately one to two millimeters between the respective ends. Electrical connection is made via fine insulated wires from the inner and outer needles to the connectors which attach to the coagulator.

Statement of indications for use. - For Illumination, coagulation, and tissue manipulation during ophthalmic surgery

K980530

Substantial Equivalence Comparison

Design	Peregrine F.O. Straight Bipolar Pick #100.12 *510K Application*	Peregrine F.O. Angled Bipolar Pick #100.13 *510K Application*	Grieshaber Straight Pic #630.06	Storz Straight Pick DP9605	Storz 45deg Angled Pick DP 9606	Grieshaber 3-Function Manip. #149.89
Gauge	20	20	20	20	20	20
Pick	4mm	4mm	4mm	4mm	4mm	3mm
Pick Formation	Outer Needle Straight	Outer Needle Angled	Outer Needle Straight	Outer Needle Straight	Outer Needle Angled	Inner Needle Straight

Features						
Illumination	xxx	xxx	xxx	xxx	xxx	xxx
Tissue Manipulation	xxx	xxx	xxx	xxx	xxx	xxx
Irrigation/ Aspiration						xxx
Coagulation	xxx	xxx				xxx

Materials						
Handpiece	Delrin	Delrin	Delrin	Delrin	Delrin	Delrin
Jacket	Polyethylene	Polyethylene	Polyethylene	Teflon	Teflon	Polyethylene
Connector	Aluminum	Aluminum	Aluminum	Acetal	Acetal	Acetal
Needle	20 ga Stainless	20 ga Stainless	20 ga Stainless	20 ga Stainless	20 ga Stainless	20 ga Stainless
Insulating Coating	Paralene	Paralene	none	none	none	polyamide

The proposed Peregrine Fiber Optic Bipolar Picks are a combination of identical features and designs from the two types of instruments referenced above and marketed today. The materials used are the same for the features provided except for the Paralene insulating coating used on the Bipolar Picks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 1998

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

Re: K980530
Trade Names: Peregrine Fiber Optic Bipolar Straight Pick and Peregrine Fiber Optic Bipolar Angled Pick
Regulatory Class: II
Product Code: 86 MPA
Dated: February 6, 1998
Received: February 11, 1998

Dear Mr. Richmond

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the device are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

STATEMENT OF INDICATIONS FOR USE

510K Number (if known):

Device Name: Peregrine Fiber Optic Bipolar Straight Pick
Peregrine Fiber Optic Bipolar Angled Pick

Indications for Use:

For illumination, coagulation, and tissue manipulation 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. Buck Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980530