APR 30 1998

K980399

January 30, 1998

Premarket Notification [510(k)] Summary

Submitter: Peregrine Surgical Ltd.
4050D Skyron Drive
Doylestown, PA 18901
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Official Correspondent: Amy Hessenthaler

Trade Name: Peregrine OptiPort Vitrectomy Probe

Common Name: Vitrectomy Guillotine Cutter

Registration Number: 2529392

Classification: Class II

Class Name: Not Known

Panel: Ophthalmic

Product Code: 86 HQE

Device Description: The Peregrine OptiPort Vitrectomy Probe is a single use, 20 GA guillotine style cutter for use during ophthalmic surgery. Approximately 6' in length and provided sterile, it consists of the following. At the proximal end, a female and male luer connector attached to the resective ends of dual PVC tubing. A colored stripe is added to one of the tubes to establish it as the half used for aspiration. A Delrin Handpiece with a 20 GA stainless steel needle at the distal end. The mechanics to operate the vitrectomy probe extend through the inner lumen of the stainless shaft and may be activated pneumatically. (see Appendix B)

Statement of indications for use. - For removal of vitreous and vitreal membranes during opthalmic surgery.

Substantial Equivalence Comparison

Peregrine **OptiPort Vitrectomy Probe** **Application for 510(K)** **Product# 505.10**	**H.S. International** **Shapiro Cutter Vitrectomy Probe** **Manufactured by H.S. International** **Product# HS32-803**
Vitreous Removal	Vitreous Removal
pneumatic driver	pneumatic driver
guillotine cutting action	guillotine cutting action
20 GA stainless steel shaft	20 GA stainless steel shaft
.035mm port at distal tip	.034mm port at distal tip
insertion through 1mm incision	insertion through 1mm incision
single use	single use
ergonomic handle	ergonomic handle

The Peregrine OptiPort Vitrectomy Probe is identical in principle to the ophthalmic guillotine cutters marketed today. The materials used in its manufacture are similar, if not in most comparisons identical.

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

APR 30 1998

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

Re: K980399
Trade Name: Peregrine OptiPort Vitrectomy Probe
Regulatory Class: II
Product Code: 86 HQE
Dated: January 30, 1998
Received: February 2, 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): K980399

Device Name: Peregrine OptiPort Vitrectomy Probe

Indications for Use:

For removal of vitreous and vitreal membranes 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_____

Evenette T. Beam

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980399