K981907

Peregrine

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

AUG 4 1998

May 28, 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: V.F.I. (Viscous Fluid Injection) Tubing Set

Common Name: Viscoelastic Infusion Tubing Set

Registration Number: 2529392

Classification: Class II

Class Name: Not Known

Panel: Ophthalmic

Product Code: MRH

Device Description: The Peregrine V.F.I. Tubing Set is 8' in length and designed to infuse silicone oil into the posterior segment of the eye. It consists of the following: A connector at the proximal end to fit into a pneumatic injection system, 8' PVC tubing running from the connector and attaching to a Delrin Syringe Head which incorporates a .2um filter, and a syringe assembly (Terumo) which is attaches to the syringe head.

Statement of Indications for use. - For pneumatic infusion of silicone oil into the posterior segment.

Substantial Equivalence Comparison:

Peregrine V.F.I. **Tubing Set** **Application for 510(K)** **Product# 300.01**	**Grieshaber & Co.** **V.I.S. Pack Tubing Set** **Manufactured by Grieshaber & Co.** **Product# 629.30**
Silicone Oil Infusion	Silicone Oil Infusion
nylon connectors	nylon connectors
PVC Tubing 8'	PVC Tubing 8'
Delrin Syringe Head	Delrin Syringe Head
Terumo Syringe 35cc	Terumo Syringe 35cc
Gelman .2um filter	Gelman .2um filter
Single Use	Single Use

The Peregrine V.F.I. Tubing Set, product #PD300.01, is identical to the Grieshaber V.I.S. Pack with the exception of the labeling specifications.

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

AUG 4 1998

Mr. Todd Richmond
Director of Product Development
Peregrine Surgical LTD.
4050 D Skyron Drive
Doylestown, PA 18901

Re: K981907
Trade Name: V.F.I.-Viscous Fluid Infusion Tubing Set
Regulatory Class: II
Product Code: 86 MRH
Dated: May 28, 1998
Received: June 1, 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: V.F.I. (Viscous Fluid Injection) Tubing Set

Indications for Use:

For pneumatic infusion of silicone oil into the posterior segment.

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 K980797