3/25/99

K990518

Peregrine

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

March 18, 1999

Premarket Notification [510(k)] Summary

Submitter: Peregrine Surgical Ltd.
4050D Skyron Drive
Doylestown, PA 18901
Phone: (215) 348-0456
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Official Correspondent: Amy Hessenthaler

Trade Name: Peregrine Wet Set

Common Name: Air/Fluid Tubing Set

Registration Number: 2529392

Classification: Class II

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: 80 FRN

Device Description: The Peregrine Wet Set is an 8' tubing set designed to deliver humidified air or fluid into the eye during ophthalmic surgery. It consists of the following: An 8' PVC tube running from an air supply unit to a three channel IV spike for insertion into a bottle of Balanced Salt Solution. The three way spike is designed to inject the air from the air supply unit through the solution, while at the same time deliver humidified air and saline through a dual PVC tube. The dual PVC tube is designed to transport the humidified air in one side and the saline in the other. The dual PVC tube attaches at the other end to a three way stopcock.

Statement of indications for use. - For the delivery of forced humidified air or fluid during ophthalmic surgery.

Substantial Equivalence Comparison:

FEATURES	GRIESHABER GLOBAL CONTROL	ALCON VGFI TUBING SET	PEREGRINE WET SET
Number of channels in drip chamber spike:	2	2	3
Pressurized air enters bottle	/INTO FLUID	/INTO AIR SPACE	/INTO FLUID
Pressurized air to stopcock delivered from	AIR SYSTEM	AIR SYSTEM	BOTTLE
Fluid Source	BOTTLE	BOTTLE	BOTTLE
Air system required	YES	YES	YES
Bottle hung at eye level	YES	YES	YES
Bottle pressurized by air system	YES	YES	YES
Delivery line for fluid to stopcock	YES	YES	YES
Delivery line for air to stopcock	YES	YES	YES
3 way stop cock for air/fluid selection	YES	YES	YES
Filter at air line attachment to system	YES	YES	YES
Extension tube into bottle air space	NO	YES	YES

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 25 1999

Mr. John E. Richmond
President
Peregrine Surgical Limited
4050 D Skyron Drive
Doylestown, PA 18901

Re: K990518
Trade Name: Peregrine Wet Set
Regulatory Class: II
Product Code: 80 FRN
Dated: February 15, 1999
Received: February 18, 1999

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): K990518

Device Name: Peregrine Wet Set

Indications for Use:

For the delivery of forced humidified air or fluid 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

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990518