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K061063
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[redacted]

510(K) SUMMARY

Device Name

Classification Name:	Catheter, Peripheral, Atherectomy 21 CFR §870.4875, Class II
Common and Usual Name:	Catheter, Peripheral, Atherectomy
Proprietary Name:	SilverHawk™ Peripheral Plaque Excision System

Predicate Device

The SilverHawk™ Peripheral Plaque Excision System (K053460), currently marketed by FoxHollow Technologies, Inc. (Redwood City, CA).

Summary

This summary of Special 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The SilverHawk™ Peripheral Plaque Excision System is intended for atherectomy of the peripheral vasculature and is not intended for use in the coronary or carotid vasculature. The SilverHawk Peripheral Plaque Excision System consists of two major components which are packaged separately, but used together during atherectomy procedures. The two components are the SilverHawk Peripheral Catheter and SilverHawk Cutter Driver.

The SilverHawk Peripheral Plaque Excision System is provided sterile for single-use. The catheter will be sterilized by Ethylene Oxide (ANSI/AAMI/ISO 11135), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6}. The cutter driver is sterilized by Gamma Sterilization Cycle (ANSI/AAMI/ISO 11137), providing a minimum SAL of 10^{-6}, with a minimum dose of 25kGy, using the VDmax method. The device is biocompatible per ISO-10993-1.

The SilverHawk Peripheral Plaque Excision System is substantially equivalent in material of construction, overall design, intended use, and safety and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device.

The SilverHawk Peripheral Plaque Excision System with labeling modifications is considered substantially equivalent to the SilverHawk Peripheral Plaque Excision System (K053460).

Contact
Melissa Murphy
Senior Regulatory Specialist
FoxHollow Technologies, Inc.
740 Bay Road
Redwood City, CA 94063
Main Tel (650) 421-8400

Date
April 14, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2006

Foxhollow Technologies, Inc.
c/o Ms. Melissa Murphy
Senior Regulatory Specialist
740 Bay Road
Redwood City, CA 94063

Re: K061063
SilverHawk™ Peripheral Plaque Excision System
Regulation Number: 21 CFR 870.4875
Regulation Name: Peripheral Atherectomy Catheter
Regulatory Class: Class II (Two)
Product Code: MCW
Dated: April 12, 2006
Received: April 17, 2006

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if known: K061063

Device Name: **SilverHawk™ Peripheral Plaque Excision System**

INDICATION FOR USE:

Indications for Use: The SilverHawk™ Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The catheter is **not** intended for use in the coronary or carotid vasculature.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahnes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061063