K100840

SECTION 5.0: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

Submitter's Name:	Hotspur Technologies, Inc.
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Date of Preparation:	July 6, 2010

JUL 12 2010

B. Subject Device

Trade Name:	EMBO-Plus Embolectomy Catheter
Common/Usual Name:	Embolectomy Catheter
Classification Name:	Catheter, Embolectomy (21 CFR 870.5150, Product Code DXE)

C. Predicate Device Name(s)

Trade Name(s):	Fogarty Thru-Lumen Embolectomy Catheter, K892410

D. Device Description:

The proposed EMBO-Plus Embolectomy Catheter is designed for the removal of fresh, soft emboli and thrombi from within vessels in the arterial system and synthetic arteriovenous dialysis fistulae. The EMBO-Plus Embolectomy Catheter is an .035" guide-wire compatible, compliant embolectomy balloon system with a proprietary valve system which allows injection of physician specified agents without the need to remove the guidewire. By providing two functions within the catheter the operator is able to remove fresh, soft emboli and thrombi from within the arterial system and synthetic arteriovenous dialysis fistulae without having to lose guidewire position.

E. Intended Use:

The Hotspur EMBO-Plus Embolectomy Catheter is indicated for use within vessels in the arterial system and synthetic arteriovenous dialysis fistulae for the removal of fresh, soft emboli and thrombi.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The proposed Hotspur EMBO-Plus Embolectomy Catheter and the predicate Fogarty Thru-Lumen Embolectomy Catheter have the same intended use. Both are indicated for removal of soft emboli and thrombi. The predicate Fogarty Thru-Lumen Embolectomy Catheter is also indicated for infusion of fluids, temporary occlusion of blood vessels and blood sampling.

The proposed Hotspur EMBO-Plus Embolectomy Catheter has similar technological characteristics as the predicate device. The catheter body of the proposed Hotspur EMBO-Plus Embolectomy Catheter is Nylon and the catheter body of the predicate Fogarty Thru-Lumen Embolectomy Catheter is PVC. The balloon of the proposed Hotspur EMBO-Plus Embolectomy Catheter is Polyurethane and the Balloon of the predicate Fogarty Thru-Lumen Embolectomy Catheter is Latex. The usable length of the proposed EMBO-Plus Catheter is 55 cm whereas the usable length of the predicate Fogarty Thru-Lumen embolectomy Catheter is available in 40 or 80 cm lengths. For removal of emboli and thrombi, inflation of the balloon is done with sterile fluid for both the proposed EMBO-Plus Embolectomy Catheter and the predicate Fogarty Thru-Lumen Embolectomy Catheter. The Fogarty Thru-Lumen Embolectomy Catheter

may also be inflated with carbon dioxide gas. The maximum inflated balloon diameter for the proposed EMBO-Plus Catheter is 15 mm whereas the predicate Fogarty Thru-Lumen Embolectomy Catheter is available in sizes up to 13 mm. The maximum guidewire size for the proposed EMBO-Plus Embolectomy Catheter is .035" which is the same guidewire size as the predicate Fogarty Thru-Lumen Embolectomy Catheter.

G. Performance Data:

Biocompatibility testing on the proposed EMBO-Plus Embolectomy Catheter has been completed. The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following Biocompatibility tests were completed:

- ISO MEM Elution Assay
- ASTM Hemolysis Assay
- Complement Activation C3a and SC5b-9 Assay
- Partial Thromboplastin Time
- Four Hour Thromboresistance Evaluation
- Materials Mediated Rabbit Pyrogen
- ISO Guinea Pig Maximization Sensitization
- ISO Acute Systemic Injection Test
- ISO Intracutaneous Reactivity Test
- Pyrogen (LAL) Chromogenic

The proposed EMBO-Plus Embolectomy Catheter was tested in-vitro and in an in-vivo animal model to confirm the performance characteristics as compared to the Edwards Fogarty Thru-Lumen Embolectomy Catheter predicate device. The following in-vitro performance bench tests were completed for the EMBO-Plus Embolectomy Catheter:

- Balloon Crossing Profile
- Catheter Shaft Diameter
- Guidewire Lumen Diameter
- Catheter Shaft Markings
- Balloon Working Diameter
- Balloon Inflation/Deflation Time
- Balloon Fatigue
- Catheter Body Burst Strength
- Catheter Bond and Tip Pull Strength
- Catheter Torque Strength
- Contrast Media Flow Rate
- Adherent Clot Removal
- Simulated Use/Flexibility/Kink
- Radiopacity

In-vivo testing for the EMBO-Plus Embolectomy Catheter was completed in accordance with 21 CFR Part 58 "Good Laboratory Practices for Nonclinical Laboratory Studies". Synthetic arteriovenous access grafts were surgically placed in ovine specimens and allowed to mature. Following graft maturation, a simulated procedure was performed on test and control comparator groups. Post procedure animals were survived and observed for a predetermined period. Post survival, vessel and organ histology was completed to compare vessel and organ response to the test and control device treatments.

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the EMBO-Plus Embolectomy Catheter met the established specifications necessary for consistent performance during its intended use.

H. Conclusions:

The EMBO-Plus Embolectomy Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, test protocols, and/or customer inputs. The EMBO-Plus Embolectomy Catheter is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 12 2010

Hotspur Technologies, Inc.
c/o Mr. Eric Ankerud
Executive Vice President, Clinical Regulatory and Quality
880 Maude Avenue, Suite A
Mountain View, CA 94043

Re: K100840
EMBO-Plus Embolectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: July 6, 2010
Received: July 7, 2010

Dear Mr. Ankerud:

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. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

SECTION 4.0: INDICATIONS FOR USE STATEMENT

510(k) Number: K100840

Device Name: EMBO-Plus Embolectomy Catheter

Indication For Use: The EMBO-Plus Embolectomy Catheter is indicated for use within vessels in the arterial system and synthetic arteriovenous dialysis fistulae for the removal of fresh, soft emboli and thrombi.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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. VanAusdall

(Division Sign-Off)
Division of Cardiovascular Devices

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