K100842

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

JUL 12 2010

A. Submitter Information

Submitter's Name:	Hotspur Technologies, Inc.
Address:	880 Maude Ave., Suite A Mountain View, CA 94043
Telephone:	650-969-3150
Fax:	408-608-1597
Contact Person:	Eric Ankerud, Executive Vice President Clinical, Regulatory, Quality
Date of Preparation:	July 6, 2010

B. Subject Device

Trade Name:	PTA-Plus PTA Balloon Catheter
Common/Usual Name:	Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal/Percutaneous Catheter (21 CFR 870.1250, Product Code LIT) Catheter, Embolectomy (21 CFR 870.5150, Product Code DXE)

C. Predicate Device Name(s):

Trade Name(s):	Edwards Fogarty Adherent Clot Catheter, K901625 BARD Vaccess PTA Balloon Dilation Catheter, K073472

D. Device Description:

The proposed PTA-Plus PTA Balloon Catheter is designed for de-clotting and treating stenosis in synthetic dialysis grafts. It is an .035" guide-wire compatible, PTA balloon catheter with a proprietary valve system which allows injection of contrast and an embolectomy coil for mechanical removal of thrombus.

E. Intended Use:

The PTA-Plus PTA Balloon Catheter is indicated for use within synthetic arteriovenous dialysis fistulae to remove embolic material (thrombus/debris) and dilate stenosis for treatment of obstructive lesions.

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

The proposed PTA-Plus PTA Balloon Catheter ("PTA-Plus") and the predicate Fogarty Adherent Clot Catheter have the same intended use. Both are indicated for removal of emboli from synthetic arteriovenous fistula. The predicate Fogarty Adherent Clot Catheter is also indicated for removal of emboli from native vessels in the arterial system. The proposed PTA-Plus and the predicate Bard Vaccess PTA Balloon Dilation Catheter have the same intended use. Both are indicated for treatment of obstructive lesions by dilation of the stenosis of synthetic arteriovenous dialysis fistula.

The proposed PTA-Plus PTA Catheter has similar technological characteristics as the predicate devices. The proposed PTA-Plus combines the features of the two predicate devices into one device. The proposed PTA-Plus and the Bard Vaccess PTA Balloon Dilation Catheter contain an inflatable non-compliant balloon for dilation of stenosis. The proposed PTA-Plus and the Fogarty Adherent Clot Catheter both have a coil which is expanded by manual control of the proximal handle/cable for embolectomy. The usable length of the proposed PTA-Plus PTA Balloon Catheter is 55 cm whereas the usable length of the

predicate Fogarty Adherent Clot Catheter is 80 cm and the predicate Bard Vaccess Balloon dilation Catheter is 50cm or 80cm. The proposed device and predicate devices are substantially equivalent in terms of intended use, fundamental scientific technology, target population, operating principles, and method of sterilization.

G. Performance Data:

Biocompatibility testing on the proposed PTA-Plus PTA Balloon 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 PTA-Plus PTA Balloon Catheter was tested in-vitro and in an in-vivo animal model to confirm the performance characteristics as compared to the predicate devices. The following in-vitro performance bench testing was completed for the PTA-Plus PTA Balloon Catheter:

- Balloon Crossing Profile
- Catheter Shaft Diameter
- Guidewire Lumen Diameter
- Catheter Shaft Markings
- Balloon Working Length
- Balloon Rated Burst Pressure
- Balloon Compliance/ Outer 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 PTA-Plus PTA Balloon 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 PTA-Plus PTA Balloon Catheter met the established specifications necessary for consistent performance during its intended use.

H. Conclusions:

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

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

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

JUL 12 2010

Re: K100842
PTA-Plus PTA Balloon Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, LIT
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: K100842

Device Name: PTA-Plus PTA Balloon Catheter

Indication For Use: The PTA-Plus PTA Balloon Catheter is indicated for use within synthetic arteriovenous dialysis fistulae to remove embolic material (thrombus/debris) and dilate stenosis for treatment of obstructive lesions.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100842