DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 17, 2014

Hotspur Technologies, Inc.
Mr. Eric Ankerud
Regulatory and Quality Consultant
880 Maude Avenue, Suite A
Mountain View, CA 94043

Re: K142300
Trade/Device Name: Arrow GPSCath Balloon Dilatation Catheter (150 cm)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 14, 2014
Received: August 18, 2014

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. We remind you, however, 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K142300

Device Name:

Arrow® GPSCath™ Balloon Dilatation Catheter (150 cm)

Indications for Use:

The Arrow GPSCath Balloon Dilatation Catheter (150 cm) is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

Submitter's Name: Hotspur Technologies, Inc.
A Subsidiary of Teleflex Medical, Inc.

Address: 880 Maude Avenue, Suite A
Mountain View, CA 94043

Telephone: 978-302-9467

Fax: 408-608-1597

Contact Person: Eric Ankerud

Date of Preparation: August 11, 2014

B. Subject Device

Trade Name: Arrow® GPSCath™ Balloon Dilatation Catheter (150cm)

Common/Usual Name: Balloon Catheter

Classification Name: 21 CFR 870.1250, Catheter, Angioplasty, Peripheral, Transluminal/Percutaneous Catheter

Class: II

Product Code: LIT

C. Predicate Device Name(s):

Arrow GPSCath™ Balloon Dilatation Catheter (150cm), K140351
(Hotspur Technologies)

D. Indication for Use:

The Arrow GPSCath Balloon Dilatation Catheter (150cm) is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

E. Device Description:

The Arrow GPSCath Balloon Dilatation Catheter (150cm) is an 0.014" guidewire compatible PTA balloon catheter consisting of a semi-compliant angioplasty balloon fixed at the distal tip and a novel valve technology that allows injection of fluids through the inflation lumen without removal of the guidewire. Two radiopaque markers identify the balloon working length and two radiopaque markers indentify the valve to aid in angiographic placement. The proximal portion of the catheter includes an inflation female luer lock hub on the side of the handle and a guidewire female luer lock hub in the proximal end of the handle.

Balloon inflation function is achieved using an angioplasty balloon mounted to the catheter shaft like a typical PTA balloon catheter. The fluid injection function is achieved through a valve at the proximal end of the balloon that is controlled through the device handle.

F. Predicate Device Reference:

The Arrow GPSCath Balloon Dilatation Catheter (150cm) which is the subject of this Special 510(k) is substantially equivalent in its intended use, principle of operation, and technological characteristics to the Arrow GPSCath Balloon Dilatation Catheter (150cm) that was previously cleared under K140351.

G. Performance Data:

Additional testing of key performance data, including balloon compliance, balloon rated burst pressure, and crossing profile was conducted at time zero for performance qualification resulting in an update to the Arrow GPSCath Balloon Dilatation Catheter (150cm) Compliance Chart and introducer sheath compatibility, which is the subject of this Special 510(k). All other performance data applicable to the subject device is the same as for the predicate device (K140351) since there has been no change to the device design, materials, manufacturing processes, or sterilization cycle.

H. Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation, and overall technological characteristics, Arrow GPSCath Balloon Dilatation Catheter (150cm) is determined to be substantially equivalent to the existing legally marketed Arrow GPSCath Balloon Dilatation Catheter (150cm) device.