

Hotspur Technologies, Inc., A Subsidiary of Teleflex Medical, Inc.
Traditional 510(k) Notification
Arrow GPSCath Balloon Dilatation Catheter (150 cm)

JUL 02 2014

SECTION 5.0: 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 94943

Telephone: 978-302-9467

Fax: 408-608-1597

Contact Person: Eric Ankerud

Date of Preparation: February 7, 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):

.014 Monorail and OTW PTA Balloon Dilatation Catheters, K111295
(Boston Scientific)

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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 identify 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(s) Reference:

The Arrow GPSCath Balloon Dilatation Catheter (150cm), an extension of the previously 510(k) cleared Hotspur GPSCath product line (K101047 and K113769) was shown to be substantially equivalent in intended use, principle of operation, and technological characteristics to the following previously cleared device: .014 Monorail and OTW PTA Balloon Dilatation Catheters (K111295). The Arrow GPSCath Balloon Dilatation Catheter (150 cm) and the predicate device use common materials and design, with similar technological characteristics including working catheter length, catheter platform, balloon material, balloon length range, catheter introducer sheath compatibility, and balloon rated burst pressure. While both the subject and predicate devices have a PTA indication, the infusion capability of the Arrow GPSCath Balloon Dilatation Catheter (150 cm), with its proprietary valve design, provides the treating physician with the ability to infuse without removing the guidewire, a requirement when using the predicate device.

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G. Performance Data:

In vitro preclinical tests were performed to verify and validate the safety and effectiveness of the Arrow GPSCath Balloon Dilatation Catheter (150cm) and assure substantial equivalence to the predicate device. Functional testing of the Arrow GPSCath Balloon Dilatation Catheter (150 cm) was performed in accordance with the FDA's Guidance for PTCA Catheters and included passing data for the following tests conducted per documented procedures:

- Packaging Testing is performed to ensure that the product packaging can withstand the effects of transit and environmental conditions and still remain intact and sterile.
- Visual testing is performed to ensure that the product has not been damaged through sterilization cycle and packing testing and that the handle markings are legible.
- Dimensional Testing is performed to ensure that the product meets all dimensional performance attributes post the validated EtO sterilization cycle exposure.
- Performance Testing is conducted to ensure that the product passes all functional destructive testing post the validated EtO sterilization cycle exposure.
- Simulated Use Testing is performed in an anatomically relevant model to ensure that the product performs and meets functional attributes. Devices are then tested to ensure that there is no growth of any corrosion.

Testing was also conducted to characterize the flow rate and power injection capability for the Arrow GPSCath Balloon Dilatation Catheter (150 cm). The Arrow GPSCath Balloon Dilatation Catheter (150cm) and the predicate .014 Monorail and OTW PTA Balloon Dilatation Catheters are both balloon angioplasty catheters with equivalent operating principles and intended use.

Hotspur Technologies completed with passing results all biocompatibility testing on the Arrow GPSCath Balloon Dilatation Catheter (150cm) per the requirements of ISO 10993-1, *Biological Evaluation of Medical Devices*.

The Arrow GPSCath Balloon Dilatation Catheter (150cm) is a single use device that is supplied sterile. A sterilization validation was performed on the Arrow GPSCath Balloon Dilatation Catheter (150cm) demonstrating the device is able to be EtO sterilized to achieve a sterility assurance level (SAL) of 1×10^{-6} .

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 an existing legally marketed device.



July 2, 2014

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WC66-G609
Silver Spring, MD 20993-0002

Hotspur Technologies, Inc., a subsidiary of Teleflex Medical, Inc.
Mr. Eric Ankerud, J.D.
Acting Executive Vice President, Clinical, Regulatory, and Quality
880 Maude Avenue, St. A
Mountain View, CA 94043

Re: K140351

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: May 20, 2014
Received: May 22, 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.

Page 2 – Mr. Eric Ankerud, J.D.

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,



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

Enclosure

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STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

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

Indication 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 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)

