Traditional 510(k) Notification
Arrow GPSCath™ Balloon Dilatation Catheter

JUN 2 0 2013

510(k) SUMMARY

A. Submitter Information

Submitter's Name:	Hotspur Technologies, Inc. Subsidiary of Teleflex Medical, Inc.
Address:	880 Maude Ave., Suite A Mountain View, CA 94043
Telephone:	650-969-3150
Fax:	408-608-1597
Contact Person:	Eric Ankerud

B. Subject Device

Trade Name:	Arrow GPSCath Balloon Dilatation Catheter
Common/Usual Name:	Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal/Percutaneous Catheter (21 CFR 870.1250, Product Code LIT)

C. Predicate Device Name(s)

Trade Name(s):	GPSCath Balloon Dilatation Catheter, #K113769

D. Reference Device Name(s)

Trade Name(s):	GPSCath Balloon Dilatation Catheter (Cleared under the name PTA-Duo PTA Balloon Catheter), #K101047

E. Device Description:

The proposed Arrow GPSCath Balloon Dilatation Catheter is designed for dilation of peripheral vessels in the arterial system and native or synthetic arteriovenous dialysis fistulae in the treatment of obstructive lesions. The Arrow GPSCath Balloon Dilatation Catheter is a 0.035" guide-wire compatible, PTA balloon catheter with a proprietary proximal valve system which allows injection of fluids. By providing an angioplasty balloon with fluid delivery capability, the user is able to treat obstructive lesions within the arterial system and arteriovenous dialysis fistulae without having to lose guidewire position.

F. Intended Use:

The Arrow GPSCath Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, 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.

G. Reason for Modification:

The purpose of this Traditional 510(k) is to include additional product sizes to the GPSCath Balloon Dilatation Catheter size matrix. As a result of this change, new product codes have been established. Additionally, this Traditional 510(k) includes a dimensional change in the catheter working length and packaging, product trade name change, balloon material change, and balloon bonding process change.

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

The proposed Arrow GPSCath Balloon Dilatation Catheter and the predicate GPSCath Balloon Dilatation Catheter have the same intended use. Both are indicated for treatment of obstructive lesions by high pressure dilation in the arterial system and of native or synthetic arteriovenous dialysis fistulae.

The proposed Arrow GPSCath Balloon Dilatation Catheter and the GPSCath Balloon Dilatation Catheter contain an inflatable balloon for dilation of obstructive lesions. The proposed device and predicate device are substantially equivalent in terms of intended use, fundamental scientific technology, target population, operating principles, and method of sterilization.

I. Performance Data:

The proposed Arrow GPSCath Balloon Dilatation Catheter was evaluated using bench, biocompatibility, package and simulated use test data to confirm the performance characteristics as compared to the predicate device, the GPSCath Balloon Dilatation Catheter (#K113769). Biocompatibility testing included cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, systemic toxicity, hemolysis, complement activation, thromboresistence, partial thromboplastin time, and MEM elution. Bench top tests, specifically balloon compliance, catheter body burst strength, catheter torque strength, catheter balloon bond strength, catheter tip-pull strength, simulated use, balloon rated burst pressure, balloon fatigue, and balloon inflation/deflation time, contrast media flow rate, and catheter visual inspections were completed. All test results demonstrate that the Arrow GPSCath Balloon Dilatation Catheter met the established specifications necessary for consistent performance during its intended use.

J. Conclusions:

The Arrow GPSCath Balloon Dilatation Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, test protocols, and/or customer inputs. The Arrow GPSCath Balloon Dilatation is substantially equivalent to the legally marketed predicate device and does not raise any new safety or effectiveness questions. Minor enhancements do not affect safety or effectiveness of the device nor do they affect the functionality or indications for use of the Arrow GPSCath Balloon Dilatation Catheter. The modifications identified in this submission are documented in Hotspur's Design History File in accordance with design controls, 21 CFR 820.30, and Hotspur's internal quality system procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 20, 2013

Hotspur Technologies, Inc.
c/o Eric P. Ankerud, J.D.
Regulatory and Quality Consultant
880 Maude Avenue, Suite A
Mountain View, CA 94043

Re: K130397
Trade/Device Name: Arrow GPSCath Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: LIT
Dated: May 10, 2013
Received: May 13, 2013

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 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. 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 D. Zuckerman -S

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

Hotspur Technologies

Traditional 510(k) Notification
Arrow GPSCath™ Balloon Dilatation Catheter

STATEMENT OF INDICATIONS FOR USE

510(k) Number: _____

Device Name: Arrow GPSCath™ Balloon Dilatation Catheter

Indication For Use: The Arrow GPSCath Balloon Dilatation Catheter is indicated for use in percutaneous transluminal angioplasty of the femoral, iliac, 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)

Bram D. Zuckerman -S
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