K093056

510(k) Summary

DEC 18 2009

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Christine Ford, Sr. Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3338 Fax: 610-478-3128 Email: christine.ford@teleflexmedical.com
Date summary prepared:	September 29, 2009
Device trade name:	Arrow® Seldinger Arterial Catheterization Device
Device common name:	Arterial catheterization device
Device classification name:	Class II, DQY, Catheter, Percutaneous, 21 CFR 870.1250 Class II, DQX, Wire, Guide, Catheter, 21 CFR 870.1330
Legally marketed device to which the device is substantially equivalent:	Arrow Radial Artery Catheterization Set, K810675
Description of the device:	The Arrow Seldinger arterial catheterization devices are comprised of an introducer needle, a spring wire guide, and an arterial catheter assembly. The catheter assembly consists of a polyurethane arterial catheter molded to a winged catheter juncture hub. An extension tubing segment is molded to the proximal end of the winged catheter hub. The proximal end of the extension tubing segment is molded to a luer-locking hub. A slide clamp is provided on the extension segment.
Intended use of the device:	The Arrow Seldinger arterial catheterization devices permit access to the peripheral arterial circulation or to other small vessels.
Technological characteristics:	The proposed arterial catheterization devices use the same fundamental technology as the predicate arterial catheterization device.
Performance tests:	Verification and validation testing to support safety and efficacy included the following: - Needle penetration - Component compatibility - Leak test - Package integrity - Tensile test - Pull testing
Conclusions:	The results of verification testing demonstrate substantial equivalence of the Arrow Seldinger Arterial Catheterization device to the legally marketed predicate Arrow Radial Artery Catherization device. The differences between the proposed and predicate devices do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Arrow International, Inc.
c/o Ms. Christine Ford
Sr. Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

DEC 1 8 2009

Re: K093050
Arrow Seldinger Arterial Catheterization Devices
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY, DQX
Dated: November 25, 2009
Received: November 27, 2009

Dear Ms. Ford:

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.

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,

Donna R. McNeil

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

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)	K093050
Device Name	Arrow® Seldinger Arterial Catheterization Devices
Indications for Use	The Arrow® Seldinger Arterial Catheterization Devices permit access to the peripheral arterial circulation or to other small vessels.

Prescription Use___X___ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vehmeyer
(Division Sign-Off)
Division of Cardiovascular Devices

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