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AUG 17 2011

BUNDLED SPECIAL 510(k) SUMMARY
A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	ARROW International, Inc.
Address	2400 Bernville Road Reading, PA 19605-9607 USA
Phone number	610-378-0131, ext. 3443
Fax number	610-478-3179
Establishment Registration #	1036844 Asheboro
Name of Contact Person	Suzanne Schorle
Date prepared	July 1, 2011
Name of Device	
Trade or proprietary name	NextStep® Antegrade Chronic Hemodialysis Catheter
Common or usual name	Same as trade name
Classification name	Catheter, Hemodialysis, Implanted
Classification panel	Class III
Regulation	21 CFR Part 876.5440
Product Code(s)	MSD
Legally marketed device(s) to which equivalence is claimed	K102238 NextStep® Antegrade Chronic Hemodialysis Catheter K111117 Change in Material for Arrow International Inc. Chronic Hemodialysis Catheters
Reason for 510(k) submission	Device modification
Device descriptions	The Arrow NextStep Antegrade Chronic Hemodialysis Catheter is a one piece, two lumen, 15 Fr., step tipped catheter designed for antegrade placement. The catheter is available in multiple lengths.
Intended use of the device	The Arrow NextStep Antegrade Chronic Hemodialysis Catheter is intended for use in adult patients.
Indications for use	The Arrow NextStep Antegrade catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow NextStep Antegrade Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow NextStep Antegrade catheter is intended for use in adult patients.

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Summary of the technological characteristics of the device compared to the predicate device	The proposed devices have the same technological characteristics as the predicate device.
Summary of non-clinical tests conducted for determination of substantial equivalence	Kink and column strength tests were performed to demonstrate substantial equivalence.
Conclusions drawn from non-clinical and clinical data	Based on their respective indications for use, design, Class III Certification and Summary, and performance testing, the catheters met the requirements that are considered adequate for their intended use and demonstrate the catheters are substantially equivalent to their respective 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

Ms. Suzanne Schorle
Regulatory Affairs Specialist
Arrow International, Inc.
Subsidiary of Teleflex Medical, Inc.
2400 Bernville Road
READING PA 19605

AUG 17 2011

Re: K111900
Trade/Device Name: Arrow® NextStep™ Antegrade Chronic Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: July 1, 2011
Received: July 11, 2011

Dear Ms. Schorle:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

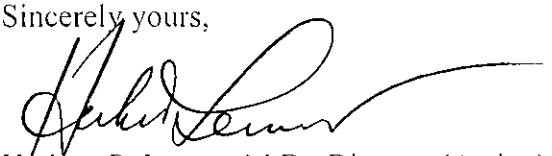
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for use Statement

510(k) Number: K111900

Device Name: Arrow® NextStep® Antegrade Chronic Hemodialysis Catheter

Indications for Use: The Arrow® NextStep® Antegrade Chronic Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. The Arrow NextStep® Antegrade Catheter is inserted percutaneously and is preferentially placed into the internal jugular (IJ) vein. Alternately, this catheter may be inserted into the subclavian vein although the jugular vein is the preferred site. Catheters greater than 40 cm are intended for femoral vein insertion. The Arrow® NextStep® Antegrade catheter is intended for use in adult patients.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111900