K102238

510(k) Summary

FEB - 1 2011

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Suzanne Schorle, Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3443 Fax: 610-478-3183 Email: suzanne.schorle@teleflexmedical.com
Date summary prepared:	October 5, 2010
Device trade name:	Arrow® NextStep™ Antegrade Chronic Hemodialysis Catheter
Device common name:	Chronic hemodialysis catheter
Device classification name:	MSD, Class III, 21 CFR Part 876.5540, Catheter, Hemodialysis, Implanted
Legally marketed devices to which the device is substantially equivalent:	Integral Chronic Hemodialysis Catheter (K040260)
Description of the device:	The Arrow® NextStep™ Antegrade Chronic Hemodialysis Catheter is a 15 Fr, 2 lumen, one piece Carbothane catheter with a preloaded stylet and step tip designed for antegrade placement. The catheter is available in multiple lengths. The procedure kit includes the necessary accessories to correctly insert the catheter.
Intended use of the device:	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 Chronic Hemodialysis 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.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate device.
Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: - Flow rate tests - Leak tests - Tensile test - Recirculation test - Biocompatibility tests
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices. Based on the indications for use, design, safety and performance testing, the Arrow® NextStep™ Anetgrade Chronic Hemodialysis Catheters met the requirements that are considered adequate for its intended use and is substantially equivalent to the predicate devices.

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KIT CERTIFICATION

We certify that all of the medical components of the subject kit are either 1) legally marketed pre-amendment devices, 2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulations and the limitations of exemptions from Section 510(k) of the Act (e.g., 21 CFR Part 862.9), or 3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which it is intended (i.e. not claiming or causing a new use for the components). Refer to Table 8 below for a list of kit components.

We further certify that Arrow International, Inc. purchases all device components either in packaged and labeled form consistent with their pre-amendments, exemption, or premarket notification criteria and status, or as bulk non-labeled and non-sterile components, also consistent with their pre-amendments, exemption, or premarket notification criteria and status.

The kit version of the device utilizes packaging that consists of a vacuum-formed tray in a poly and Tyvek® pouch. All components are placed in the tray and pouch, sealed, EtO sterilized and then packed in corrugated shipping cartons. No components are "reprocessed" as a result of the sterilization. Final processing of the kit has no effect on the functionality (i.e., safety and effectiveness) of any of the kit components.

Table 1: Kit Component Certification

Component	Device Classification	Regulation	Certification
Spring wire guide with Arrow Advancer ™	Class II, DQX 21	CFR 870.1330	K914531
SmartSeal ™2 Hemostatic Dialysis Sheath	Class II, DYB	CFR 870.1340	K043438
Introducer Needle 18 ga. X 2-1/2" (6.35 cm)	Class II, DQY	21 CFR 870.1250	K862056
Tunneler with tunneling sheath	Class II	21 CFR 876.5540	K040260
Non vented male dust cap	Class II	21 CFR 870.5540	K040260
Dressing: Tegaderm®	Class I, KGX	21 CFR 880.5240	K973036
Tissue Dilator 12 Fr	Class II, DYB	21 CFR 870.1310	K780532
Tissue Dilator 14 Fr			
Arrow® SharpsAway II™ Locking Disposal Cup	Class II, FMI	21 CFR 878.4800	K041153
Safety Scalpel	Class I, GDX	21 CFR 878.4800	Exempt
CSR Wraps	Class II, FRG	21 CFR 880.6850	K800123

Suzanne Schorle 05 Oct. 2010

Suzanne Schorle date

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.
a division of Teleflex Medical, Inc.
2400 Bernville Road
READING PA 19605

FEB - 1 2011

Re: K102238
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: December 30, 2010
Received: January 3, 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,

for 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: K102238

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
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