

K122854

JAN 4 2013

510(k) SUMMARY
SUMMARY OF SUBSTANTIAL EQUIVALENCE
FOR
ARROW GLIDETHRU PEEL-AWAY SHEATH/DILATOR INTRODUCER

1. Submitter Information

Name: Arrow International, Inc. (subsidiary of Teleflex Inc.)
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Reading, PA 19605-9607
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Regulatory Affairs Specialist
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Date Prepared: January 3, 2012

2. Device Name

Device Trade Name: Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer
Common Name: Peel-Away Sheath/Dilator Introducer
Classification Name: Class II, DYB, Introducer, Catheter, 21CFR 870.1340

3. Predicate Device

Xentech Medical, Inc. Tearaway Introducer Sheath (K000313)

4. Device Description

The Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer is a single use introducer designed to facilitate insertion of a device into the vasculature. The Peel-Away Sheath/Dilator Introducer Assembly is a unit comprised of a peel-away sheath introducer and a dilator. The Peel-Away sheath has a non-tapered body with a tapered tip to provide a smooth transition from the dilator. The Peel-Away sheath is a radiopaque polyethylene extruded sheath body with a molded polyethylene hub. The hub is designed with wings and a thin-wall peel groove on both sides that facilitate splitting the hub and sheath after a catheter is placed through the sheath. The sheath hub is also designed to allow the dilator to lock into the sheath during the insertion procedure. The polyethylene dilator has a tapered tip and an ergonomic hub that locks into the sheath hub during the insertion procedure. The dilator hub also features a Luer lock connection on the proximal end. The Peel-Away sheath/dilator introducer is available in 3 Fr. – 7 Fr. configurations with usable lengths of 7 and 10 cm.

5. Intended Use

The Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer is used for the percutaneous introduction of diagnostic or therapeutic devices into the vasculature.

6. Technological Characteristics

The Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer is substantially equivalent to the Xentek Medical, Inc. Tearaway Introducer Sheath (K000313) in terms of intended use, general design, and functional performance.

7. Nonclinical Testing

Bench testing performed on the GlideThru™ Peel-Away Sheath/Dilator Introducer demonstrates substantially equivalent functionality to the predicate device. The following performance testing has been completed for the subject device:

- Tensile testing
- Biocompatibility
- Sheath surface free from extraneous matter
- Radiodetectability
- Luer testing
- Simulated Use testing
- Penetration/Insertion force

8. Conclusions

The subject device is similar in design and intended use to the predicate device. The results of the performance testing have demonstrated substantially equivalent functionality to the predicate device. The results of the comparison testing have demonstrated that the GlideThru is comparable to the predicate device in the following aspects: radiopacity, tensile strength, and penetration/insertion force. Any differences between the subject and predicate sheath introducers do not raise new issues of safety or effectiveness. The Arrow GlideThru™ Peel-Away Sheath/Dilator Introducer is substantially equivalent to the Xentek Medical, Inc. Tearaway Introducer Sheath.



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

JAN 4 2013

Arrow® International, Inc.
c/o Julie Lawson
Regulatory Affairs Specialist
Arrow® International, Inc
2400 Bernville Road
Reading, PA 19605

Re: K122854

Trade/Device Name: Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer
Arrow® Pressure Injectable Jugular Axillo-subclavian Central
Catheter™ with Chlorag⁺ard® Antimicrobial and Antithrombogenic
Technology

Regulation Number: 21 CFR 870.1340

Regulation Name: Introducer, Catheter

Regulatory Class: Class II

Product Code: DYB

Dated: December 19, 2012

Received: December 20, 2012

Dear Ms. Lawson:

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 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" (21 CFR 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,

Matthew G. Hillebrenner

for

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

Enclosure

Indications for Use

510(k) Number (if known): K122854

Device Name: Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer

Indications for Use:

The Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer is used for the percutaneous introduction of diagnostic or therapeutic devices into the vasculature.

Indications for Use (JACC product):

The Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter™ with Chlorag+ard® Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable JACC™ may not exceed 300 psi. The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

Chlorag+ard Technology treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization on catheter surfaces. Antimicrobial effectiveness was evaluated using *in vitro* and *in vivo* test methods and no correlation between these testing methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122854

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