

NOV 18 2011

5. 510(k) Summary

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: 610-478-3179 Email: christine.ford@teleflex.com
Date summary prepared:	August 31, 2011
Device trade name:	TransRadial Artery Access Device
Device common name:	Percutaneous sheath introducer
Device classification name:	Class II, DYB, Introducer, Catheter, 21 CFR 870.1340
Legally marketed device to which the device is substantially equivalent:	Arrow Percutaneous Sheath Introducers, K780532 Terumo Glidesheath™ Catheter Introducer Sheath, K082644
Description of the device:	The TransRadial Artery Access devices are comprised of the components required to perform percutaneous transradial artery access: an introducer needle, a guide wire, a dilator, and a percutaneous sheath introducer with hemostasis valve and sidearm assembly with a stopcock.
Intended use of the device:	The TransRadial Artery Access Device is intended for use for percutaneous introduction of devices into the radial artery for diagnostic and therapeutic purposes.
Technological characteristics:	The TransRadial Artery Access devices use the same fundamental technology as the aforementioned predicate percutaneous catheter introducer devices. All provide the device components necessary for introduction of a catheter into a vessel using the Seldinger technique.
Performance tests:	To demonstrate safety and functional efficacy of the TransRadial Artery Access devices, the following tests were performed on the device components and met acceptability requirements: <ul style="list-style-type: none">• Biocompatibility in accordance with ISO 10993-1: cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, hemocompatibility, and rabbit pyrogen• Introducer needle testing: surface, bevel, and needle point visual inspections, corrosion resistance, radiodetectability, hub to

cannula and guidewire interface, hub female luer lock testing (air and liquid leakage, separation force, unscrewing torque, ease of assembly, resistance to overriding, and stress cracking), strength of union of needle tube and needle hub, penetration force, and needle bevel alignment and dimensional analysis

- Sheath introducer testing: surface visual inspection, radiodetectability, freedom from leakage from sheath introducer, freedom from leakage through hemostasis valve, sidearm stopcock hub luer lock testing (air and liquid leakage, separation force, unscrewing torque, ease of assembly, resistance to overriding, and stress cracking), force at break between sheath introducer and the junction between sheath introducer and the hub (hemostasis valve), and force at break between hemostasis valve body barb to side arm extrusion and side arm extrusion to stopcock
- Guide wire testing: surface visual inspection, lateral stiffness, corrosion resistance, radiodetectability, fracture, flexing, strength of union of core wire and coil, and tensile strength pull testing
- Dilator testing: surface visual inspection, radiodetectability, dilator hub luer slip testing (air and liquid leakage, separation force, stress cracking), and strength of union between hub and dilator
- Sheath/dilator assembly testing: sheath/dilator rollback upon insertion, sheath/dilator insertion force, sheath/dilator assembly rigidity, and sheath and dilator dimensional inspections
- Overall device component compatibility testing

Conclusions:

The described intended use, results of verification testing performed, and comparison testing to the predicate devices demonstrated that the subject devices are substantially equivalent to the legally marketed predicate intravascular catheter introducer devices, the Arrow Percutaneous Sheath Introducers and Terumo Glidesheath™ Catheter Introducer Sheath. Any 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 -WO66-G609
Silver Spring, MD 20993-0002

NOV 18 2011

Arrow International, Inc.
Subsidiary of Teleflex Medical Inc.
c/o Christine Ford
Senior Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

Re: K112554

Trade/Device Name: Arrow TransRadial Artery Access Device
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 30, 2011
Received: September 2, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you 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.

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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,



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

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k)
Number
(if known)

K112554

Device Name TransRadial Artery Access Devices

Indications
for Use

The TransRadial Artery Access Device is intended for use for percutaneous introduction of devices into the radial artery for diagnostic and therapeutic purposes.

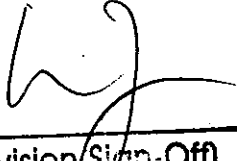
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112554