K040100

MAR - 1 2004

510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	William G. McLain Manager, Regulatory Affairs Phone: 610-378-0131, ext. 3323 Fax: 610-478-3188 Email: bill.mclain@arrowintl.com
Date summary prepared:	January 16, 2004
Device trade name:	Arrow Echogenic Introducer Needle, a component of Peripherally Inserted Central Catheter Sets
Device common name:	Introducer Needle
Device classification name:	DQX; 21 CFR Part 870.1330; Accessory to Catheter Guidewire
Legally marketed devices to which the device is substantially equivalent:	Arrow International, Inc.'s PICC Two-Lumen Peripherally Inserted Central Catheter Set (K930129). Cook's 21Ga needle will also be used as a predicate. 510(k) number unknown.
Description of the device:	The Peripherally Inserted Central Catheter Kits contains many of the components required for the user to place the PICC. An introducer needle is used to gain access to the vein. A guidewire is then placed through the introducer to provide a track for the remaining devices. After removal of the introducer needle from the vein, the guide wire is left in place and a dilator/peel-away introducer assembly is advanced into the vessel thereby enlarging the subcutaneous track. When positioned, the dilator is removed and the peel-away introducer remains along with the guide wire. The PICC is placed through the introducer catheter. After catheter positioning is confirmed, the guide wire and peel-away introducer are removed. A "Stat-Lock" catheter fixation device secures the catheter during use.

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Intended use of the device:	An introducer needle allows access to the vasculature for introduction of a guidewire. A peripherally inserted Central Catheter permits venous access to the central circulation through a peripheral vein.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate device(s).
Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: - Needle penetration - Hub bond tensile strength test
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. William G. McLain
Manager, regulatory Affairs
ARROW International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

Re: K040100
Trade/Device Name: Arrow Echogenic Introducer Needle a Component of Peripherally Inserted Cental Catheter Sets
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: January 20, 2004
Received: January 20, 2004

Dear Mr. McLain:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number:	K040100
Device Name:	Arrow Echogenic Introducer Needle, a component of Peripherally Inserted Central Catheter Sets
Indications for Use:	The Arrow Echogenic Introducer Needle allows access to the vascular system for the introduction of a guidewire. A peripherally inserted central catheter permits venous access to the central circulation through a peripheral vein. It offers an alternative method of intravenous therapy for select adult and pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anne Naveau for WMB

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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PRESCRIPTION USE X