K042126

AUG 27 2004

ATTACHMENT 1: 510 (K) SUMMARY

Submitter	ARROW International Inc 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Suzanne Schorle Regulatory Affairs Associate Phone: 610-378-0131, ext. 3443 Fax: 610-478-3167 Email: suzanne.schorle@arrowintl.com
Date summary prepared:	August 4, 2004
Device trade name:	Peripherally Inserted Central Catheters
Device common name:	PICC
Device classification name:	Catheter, intravascular, therapeutic, long-term greater than 30 days
Legally marketed devices to which the device is substantially equivalent:	Arrow International's Peripherally Inserted Central Catheter (K930129) and Two Lumen PICC with Blue FlexTip® Catheter with Integral Needle Protection (K003006)
Description of the device:	The Arrow International Peripherally Inserted Central Catheters are similar to the currently marketed Arrow Trimmable and Blue FlexTip® single and double lumen catheters. The catheter juncture has been modified to improve overall catheter strength. The hub colors and catheter labeling have changed to distinguish the new Arrow catheters. The catheter is available in lengths of 40 cm – 60 cm.
Intended use of the device:	The Arrow International Peripherally Inserted Central Catheter is intended for short-term peripheral venous access to the central circulation. It offers an alternative method of intravenous therapy for select adult and pediatric patients.
Technological characteristics:	The proposed peripherally inserted central catheters have the same technological design characteristics as the predicate devices.
Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Tensile Strength • Flex Test • Burst • Fatigue • Leakage
Assessment of non-clinical performance data:	The results of the laboratory tests demonstrate that the Arrow peripherally inserted central catheter are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2004

Ms. Suzanne Schorle
Regulatory Affairs Associate
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K042126
Trade/Device Name: Peripherally Inserted Central Catheter
Regulation Number: 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter.
Regulatory Class: II
Product Code: LJS
Dated: August 5, 2004
Received: August 6, 2004

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 (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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in your Indications For Use Statement and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings of device's labeling:

- The safety and effectiveness of this device for the use with power injection and high power infusion systems has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

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

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042126

ATTACHMENT 2: INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: Peripherally Inserted Central Catheter

Indications for Use: 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.

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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

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