K061289

AUG 24 2006

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Reading, PA 19612

ARROW
INTERNATIONAL

2400 Bernville Road
Reading, PA 19605

(610) 378-0131
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510 (k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Elizabeth Duncan Senior Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3220 Fax: 610-478-3172 Email: elizabeth.duncan@arrowintl.com
Date summary prepared:	May 5, 2006
Device trade name:	Pressure Injectable Peripherally Inserted Central Catheter (21 CFR 880.5970, Product Code LJS)
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:	AngioDynamic's Morpheus™ CT PICC and Procedure Kit (K041420) and Arrow International's Peripherally Inserted Central Catheter (K042126)
Description of the device:	The Arrow PICC have the following characteristics: • Radiopaque polyurethane cathteters • 4 Fr Single Lumen, trimmable • 5 Fr Double Lumen, trimmable and BlueFlex® Tip • Usable lengths of 5 French catheter is 40 and 60 cm • Usable length of 4 French catheter is 60 cm • Catheters are provided sterile kit configurations. • The catheter is labeled for "4cc/pressure injectable" on the catheter distal hub to facilitate the proper use of the device.
Intended use of the device:	The Arrow Pressure Injectable PICC is intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.

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Indications for use:	The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion and power injection of contrast media. The maximum pressure of power injector equipment used with the pressure injectable PICC may not exceed 300 psi.
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: • Dynamic Flow Rate test • Catheter whip test • Repeat Injection Test
Assessment of non-clinical performance data:	The results of the bench tests demonstrate that Arrow's peripherally inserted central catheter is as safe, as effective and performs favorably when compared to the AngioDynamic's catheter.
Summary	Arrow International's peripherally inserted central catheter has the same intended use as the AngioDynamic's predicate device. Based on the assessment of non-clinical performance data to verify this new intended use, and the technological characteristic comparison, Arrrow's peripherally inserted central catheter is substantially equivalent to the legally marketed predicate device. The Arrow International's predicate device was used as a reference device to show the primary design has not changed significantly and that proper verification was done to prove the catheter can be used safely for its new indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2006

Ms. Elizabeth Duncan
Senior Regulatory Affairs Specialist
ARROW International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

Re: K061289
Trade/Device Name: Arrow Pressure Injectable PICCs, Models
5 French 2 lumen 60 cm Trimmable
5 French 2 lumen 40 cm Blue Flex Tip (nontrimmable)
4 French 1 lumen 60 cm Trimmable
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 19, 2006
Received: July 20, 2006

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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.

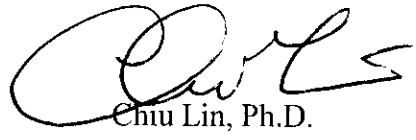
If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. 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/industry/support/index.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

K061289

Indications for Use Statement

510(k) Number (if known):

Device Name: Pressure Injectable PICC

Indications For Use: The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion and power injection of contrast media. The maximum pressure of power injector equipment used with the pressure injectable PICC may not exceed 300 psi.

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 IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. [signature]

...n Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...) Number: K061289