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510(k) Summary

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605-9607 USA

JAN 15 2008

Contact person:	Kevin Lentz Regulatory Affairs Project Manager Phone: 610-378-0131 Fax: 610-478-3172 Email: kevin.lentz@teleflexmedical.com
Date summary prepared:	December 7, 2007
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 which the device is substantially equivalent:	Arrow International's Peripherally Inserted Central Catheter (K061289)
Description of the device:	The Pressure Injectable Peripherally Inserted Central Catheters have the following characteristics: • Radiopaque polyurethane catheters • 4 Fr single-lumen BlueFlex® Tip and non-BlueFlex® Tip • 5 Fr double lumen BlueFlex® Tip and non-BlueFlex® Tip • Usable length of 4 Fr catheters are 40cm to 60cm • Usable length of 5 Fr catheters are 40cm to 60cm • Catheters are provided in sterile kit configurations • The 4 Fr BlueFlex® Tip, 4Fr non-BlueFlex® Tip and 5 Fr BlueFlex® Tip catheters are labeled for "4ml/sec, pressure injectable" on the Luer hub(s) to facilitate the proper use of the device • The 5 Fr non-BlueFlex® Tip catheter is labeled for "5ml/sec, pressure injectable" on the Luer hubs to facilitate the proper use of the device

Intended use of the device:	The Arrow International Pressure Injectable PICC is intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.
Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Flow Rate Qualification Test • Repeat Injection Test • Catheter Static Burst Pressure (after sterilization, simulated shipping conditions, cleaning solutions, repetitive bending of catheter, and use of high vesicant fluid on catheter)
Assessment of non-clinical performance data:	The Arrow International Pressure Injectable PICC met performance criteria of the safety and effectiveness tests performed based on FDA recognized standards and guidance. The results of bench tests demonstrate that Arrow's PICC's are as safe and effective as compared to the predicate Arrow International PICC (K061289).
Summary:	Arrow International's Pressure Injectable Peripherally Inserted Central Catheter (PICC) has the same intended use as the predicate device, Arrow International's PICC, (K061289). Based on the assessment of non-clinical performance data, Arrow International's Pressure Injectable Peripherally Inserted Central Catheter (PICC) is substantially equivalent to the legally marketed predicate device. The Arrow International predicate device (K061289) was used as a reference device to show the primary design has not changed significantly and that proper verification was done to prove that the catheter can be used safely for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 15 2008

Mr. Kevin Lentz
Regulatory Affairs Project Manager
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

Re: K073451
Trade/Device Name: Pressure Injectable PICC
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: January 4, 2008
Received: January 7, 2008

Dear Mr. Lentz:

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 (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

Indications for Use Statement

510(k) Number : K073451

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)

[illegible] of Anesthesiology, General Hospital,
[illegible] Control, Dental Devices

[illegible] Number K073451