

510(k) Summary

JUN 27 2008

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

Contact person: Julie Lawson
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Date summary prepared: February 29, 2008

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 (K073451) and Bard Access Systems, 6 Fr Triple Lumen PowerPICC® (K053501) and Central Venous Pressure Monitoring (K051991).

Description of the device: The Pressure Injectable Peripherally Inserted Central Catheters have the following characteristics:

- Radiopaque polyurethane catheters
- 6 Fr Triple Lumen BlueFlex® Tip
- Usable length of catheters are 40 cm to 55 cm
- Catheters are provided in sterile kit configurations
- The 6 Fr BlueFlex® Tip catheter is labeled for "6 ml/sec, pressure injectable" on the Luer hub 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:

- Liquid Leakage Under Pressure
- Air Leakage During Aspiration
- Air Leakage Under Pressure
- Catheter and Blue Flex Tip Stiffness
- Catheter Collapse
- Tensile Testing
- Catheter Radiopacity
- Non-Pressure Injectable Lumen Static Burst Pressure
- Repeat Pressure Injection
- Static Burst Pressure under power injection
- Central Venous Pressure Monitoring

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 Pressure Injectable PICC (K073451) and Bard Access Systems, 6 Fr Triple Lumen PowerPICC® (K053501) and Central Venous Pressure Monitoring (K051991).

Summary:

Arrow International's 6 Fr. Triple Lumen Pressure Injectable Peripherally Inserted Central Catheter (PICC) has the same intended use as the predicate device, Arrow International's PICC. 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 devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Juie Lawson
Regulatory Affairs Specialist
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

Re: K080604
Trade/Device Name: Pressure Injectable PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: June 5, 2008
Received: June 9, 2008

Dear Ms. Lawson:

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

K080604

Indications for Use Statement

510(k) Number: K 080604

Device Name: 6 French Triple Lumen Pressure Injectable PICC

Indications For Use:

The 6 Fr. Triple Lumen Pressure Injectable Peripherally Inserted Central Catheter is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, power injection of contrast media, and allows for central venous pressure monitoring. 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) (21CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K080604