SECTION 4 – 510k Summary: AUG 30 2007

In accordance with 21 CFR 807.87(h), the following 510(k) summary has been prepared per 21 CFR 807.92.

Pressure Injectable Central Venous Catheter 510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Kirsten Stowell Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3514 Fax: 610-478-3128 Email: kirsten.stowell@arrowintl.com
Date summary prepared:	June 1, 2007
Device trade name:	Arrow Central Venous Catheter ARROWg+ard Blue® Central Venous Catheter ARROWg+ard Blue PLUS® Central Venous Catheter
Device common name:	Central Venous Catheter (CVC)
Device classification:	Catheter, intravascular, therapeutic, short-term less than 30 days; Product Code FOZ; 21 CFR 880.5200, Class II
Legally marketed devices to which the device is substantially equivalent:	Arrow Standard Multiple Lumen CVC with Blue FlexTip® (K862056, SE date 8/25/1986) ARROWg+ard Blue® CVC (K900263, SE date 7/24/1990 and K962577, SE date 8/27/1997) ARROWg+ard Blue PLUS® CVC (K993691, SE date 3/8/2000) Bard Access System, Inc PowerHickman (K061179, SE date 8/9/2006) Arrow Berman Angiographic Catheter devices (K892530, SE date 9/26/1989)
Description of the device:	The Arrow CVC have the following characteristics: • Radiopaque polyurethane catheters • 16Ga, 1 Lumen • 7Fr through 8.5Fr, 2 through 4-Lumens • Usable lengths of 16 – 20cm • Catheters are provided sterile kit configurations. • The catheter is labeled with the maximum flow rating on the catheter distal hub to facilitate the proper use of the device.

Intended use of the device:	The intended use is the same as the predicate devices.
Indications for use:	The Indications for Use were expanded to include: "*The injection of contrast media. When used for the pressure injection of contrast media, do not exceed the maximum labeled flow rate. The maximum pressure of power injector equipment used with the pressure injectable CVC may not exceed 400psi.*"
Technological characteristics:	The proposed central venous catheters have the same technological design characteristics as the predicate CVC devices.
Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Flow rate Qualification Test • Repeat Injection Test • Catheter Burst Pressure Test
Assessment of non-clinical performance data:	The Arrow Pressure Injectable CVC met performance criteria of the safety and effectiveness tests performed based on FDA recognized standards and guidance. The results of the bench tests demonstrate that Arrow's central venous catheters are as safe and effective as compared to the currently marketed predicate catheters.
Assessment of clinical performance data:	Two studies evaluated the feasibility, safety and efficacy of the use of the Arrow International's central venous catheters for the purpose of power injection of contrast media during diagnostic imaging procedures. Arrow International's Pressure Injectable CVC devices have been demonstrated to be safe and effective for the high pressure administration of contrast media when hospital guidelines and injection protocol are followed.
Summary	Arrow International's central venous catheter has the same intended use as the predicate devices. Based on the assessment of non-clinical and clinical performance data to verify this new intended use, and the technological characteristic comparison, Arrow's central venous catheter is 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

Ms. Kirsten Stowell
Regulatory Affairs Specialist
Arrow International, Incorporated
2400 Bernville Road, PO Box 12888
Reading, Pennsylvania 19605

AUG 3 0 2007

Re: K071538
Trade/Device Name: ARROWg+ard Blue® Central Venous Catheter
ARROWg+ard Blue PLUS® Central Venous Catheter
Arrow Central Venous Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: June 4, 2007
Received: June 5, 2007

Dear Ms. Stowell:

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 (if known): K071538

Device Name: ARROWg+ard Blue® Central Venous Catheter

The ARROWg+ard Blue® antimicrobial catheter is indicated to permit short-term (<30 day) central venous access for the treatment of diseases or conditions requiring central venous access, including, but not limited to the following:

- Lack of usable peripheral IV sites
- Central venous pressure monitoring
- Total parenteral nutrition (TPN)
- Infusions of fluids, medications, or chemotherapy
- Frequent blood sampling or receiving blood transfusions/blood products
- Injection of contrast media

When used for pressure injection of contrast media, do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with the pressure injectable CVC may not exceed 400psi.

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)

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

510(k) Number: K071538

Indications for Use Statement

510(k) Number (if known): K071538

Device Name: ARROWg+ard Blue PLUS® Central Venous Catheter

The ARROWg+ard Blue PLUS® antimicrobial multiple-lumen catheter is indicated to permit short-term (<30 day) central venous access for the treatment of diseases or conditions requiring central venous access, including, but not limited to the following:

- Replacement of multiple peripheral sites for IV access
- Lack of usable peripheral IV sites
- Central venous pressure monitoring
- Total parenteral nutrition (TPN)
- Infusion of incompatible medications
- Multiple infusions of fluids, medications, or chemotherapy
- Frequent blood sampling or receiving blood transfusions/blood products
- Infusions that are hypertonic, hyperosmolar, or infusions that have divergent pH values
- Injection of contrast media

When used for pressure injection of contrast media, do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with the pressure injectable CVC may not exceed 400psi.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071538

Indications for Use Statement

510(k) Number (if known): K071538

Device Name: Arrow Central Venous Catheter

The Arrow catheter is indicated to permit short-term (<30 day) central venous access for the treatment of diseases or conditions requiring central venous access, including, but not limited to the following:

- Replacement of multiple peripheral sites for IV access
- Lack of usable peripheral IV sites
- Central venous pressure monitoring
- Total parenteral nutrition (TPN)
- Infusion of incompatible medications
- Multiple infusions of fluids, medications, or chemotherapy
- Frequent blood sampling or receiving blood transfusions/blood products
- Infusions that are hypertonic, hyperosmolar, or infusions that have divergent pH values
- Injection of contrast media

When used for pressure injection of contrast media, do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with the pressure injectable CVC may not exceed 400psi.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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