Section 13 – 510(k) Summary

a) Submitter

ARROW International, Inc.
2400 Bernville Road
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Date summary prepared: October 28, 1999

b) Device

Trade Name: ARROWg+ard Blue Plus™ Multi-Lumen Central Venous Catheter

Common Name: Antimicrobial Central Venous Catheter and Antimicrobial CVC

Classification Name: Class II at 21 CFR 880.5200, Intravascular Catheter

c) Legally marketed device to which the device is substantially equivalent

ARROWg+ard Blue® Antimicrobial Multi-Lumen Central Venous Catheter

d) Description of the device

The device is a triple-lumen, polyurethane catheter, 7 French in size, with three independent non-communicating lumens, extension lines, Luer hubs and slide clamps. It is identical in appearance and function to the ARROW predicate catheter except for the increased amount of chlorhexidine acetate and silver sulfadiazine on the external surface and the addition of the internal lumen chlorhexidine and chlorhexidine acetate impregnation.

e) Intended use of the device

The multiple-lumen catheter permits venous access to the central circulation by the way of the femoral, jugular, or subclavian veins. The ARROWg+ard Blue Plus™ antimicrobial catheter is intended to help provide protection against catheter-related infections. It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use.

f) Technological characteristics

The device has the same exact technological characteristics as the predicate, with the only differences being the increased concentration of chlorhexidine acetate and silver sulfadiazine to the catheter body outer surface and the impregnation of chlorhexidine and chlorhexidine acetate to the catheter body, extension line, and extension line hubs internal lumens.

The performance tests included in the submission include:

1) *In vitro* efficacy – zone of inhibition
2) *In vitro* efficacy – internal lumen adherence
3) *In vitro* performance – release rate test
4) Tensile tests
   a) blue tip to catheter body
   b) catheter body tensile
   c) catheter body to juncture hub
   d) extension line to juncture hub
   e) extension line tensile
   f) extension line to extension line hub
5) Fatigue life testing
6) Stability tests
7) Biocompatibility tests

The *in vivo* performance tests included in the submission include:

1) *In vivo* swine safety study
2) *In vivo* half-life study
3) *In vivo* delayed inoculum study

The results of the laboratory tests demonstrate that the device is as safe as and is more effective than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K993691
Trade Name: ARROWg+ard Blue Plus™ Antimicrobial
Multi-Lumen Central Venous Catheter Kit
Regulatory Class: II
Product Code: FOZ
Dated: January 3, 2000
Received: January 4, 2000

Dear Mr. Nickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains the following: three swabstick foil pack 10% povidone-iodine and one 5 mL ampule HCL, 1% Lidocaine solution which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 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 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the

regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K993691

Section 14 – Indications for Use

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

- multiple peripheral sites for IV access
- lack of usable peripheral IV sites
- central venous pressure monitoring
- total parenternal nutrition (TPN)
- 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

There are no specific CDC guidelines for maximum indwelling times or catheter exchanges. Catheters should remain indwelling or should be exchanged per hospital protocol.

Nick Hilliard for Pat Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993691