K083675 page 1 of 2

MAR 19 2009

**510(k) Summary**
**21 CFR 807.92(a)**

**Power-Trialysis™** Short Term Dialysis Catheter Family
March 5, 2009

**General Provisions**

| | |
|---|---|
| Submitter of 510(k) Premarket Notification: | Bard Access Systems, Inc. (BAS)<br>[Subsidiary of C.R. Bard, Inc.]<br>Salt Lake City, Utah 84116<br>Phone: (801) 595-0700, Ext. 5651<br>Fax: (801) 595-5425 |
| Contact Person: | Jessica Agnello<br>Regulatory Affairs Specialist |
| Device Trade Name: | **Power-Trialysis™** |
| Device Generic Name: | Short Term Dialysis Catheter |

**Predicate Devices**

| | |
|---|---|
| Trade Name: | **Niagara® Slim-Cath®** Catheters |
| Common/Usual Name: | Short-Term Hemodialysis Catheter |
| Classification Name: | 78 MPB–Catheter, Hemodialysis, Non-Implanted |
| CFR Reference: | 21 CFR §876.5540(b)(2), Class II |
| Classification Panel: | Gastroenterology and Urology |
| Premarket Notification: | See below |

| Predicate Device Name | 510(k) | Concurrence Date |
|---|---|---|
| **Niagara® Slim-Cath®** Short Term Dialysis Catheters | K010778 | April 13, 2001 |

| | |
|---|---|
| Trade Name: | **PowerPICC®** Catheters |
| Common/Usual Name: | Peripherally Inserted Central Catheter (PICC) |
| Classification Name: | 80 LJS– Long Term Intravascular Catheter |
| CFR Reference: | 21 CFR §880.5970, Class II |
| Classification Panel: | General Hospital |
| Premarket Notification: | See below |

| Predicate Device Name | 510(k) | Concurrence Date |
|---|---|---|
| 6 Fr Triple Lumen (TL) **PowerPICC®** catheter | K053501 | January 13, 2006 |
| Central Venous Pressure Monitoring – PICCs and CVC Catheters | K051991 | October 20, 2005 |

| | |
|---|---|
| Trade Name: | **Mahurkar®** Triple Lumen Catheter |
| Common/Usual Name: | Catheter, Hemodialysis, Triple-Lumen, Non-implanted |
| Classification Name: | 78 NIE |
| CFR Reference: | 21 CFR §876.5540, Class II |
| Classification Panel: | Gastroenterology and Urology |
| Premarket Notification: | See below |

| Predicate Device Name | 510(k) | Concurrence Date |
|---|---|---|
| **Mahurkar**® Triple Lumen Catheter | K020089 | January 9, 2002 |

**Classification**

21 CFR §876.5540(b)(2), Class II,
78 NIE–Catheter, Hemodialysis, Triple Lumen, Non-Implanted

**Performance Standards**

Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

**Intended Use**

The **Power-Trialysis**™ Short-Term Dialysis Catheter, with a third internal lumen for intravenous therapy, power injection of contrast media, and central venous pressure monitoring, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media.

**Indications for Use**

The **Power-Trialysis**™ Short-Term Dialysis Catheter, with a third internal lumen for intravenous therapy, power injection of contrast media, and central venous pressure monitoring, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media.

**Technological Characteristics**

Technological similarities between the subject **Power-Trialysis**™ catheters and the predicate devices remain identical. There are no new questions raised regarding safety or efficacy of the **Power-Trialysis**™ catheters.

**Summary of Substantial Equivalence**

Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Power-Trialysis**™ catheters met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available catheters/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2009

Ms. Jessica Agnello
Regulatory Affairs Specialist
C.R. Bard, Inc.
Bard Access Systems, Inc.
605 North 5600 West
SALT LAKE CITY UT 84116

Re: K083675
Trade/Device Name: **Power-Trialysis™** Short-Term Dialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NIE
Dated: March 9, 2009
Received: March 10, 2009

Dear Ms. Agnello:

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 (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 (PMA), 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 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.

In addition, we have determined that your device kit contains Chloraprep Applicator, Sodium Chloride Solution, and Lidocaine, 1%, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug component[s] 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 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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K083675

Device Name: **Power-Trialysis™** Short-Term Dialysis Catheter

Indications for Use:

The **Power-Trialysis™** Short-Term Dialysis Catheter, with a third internal lumen for intravenous therapy, power injection of contrast media, and central venous pressure monitoring, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media.

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, & Radiological Devices
510(k) Number K083675