5.1 General Information

Submitter Name: Bard Access Systems, Inc. (BAS)
[Wholly owned Subsidiary of C. R. Bard, Inc.]
Address: 5425 West Amelia Earhart Drive
Salt Lake City, UT 84116
Telephone Number: (801) 595-0700 ext. 7136
Fax Number: (801) 595-5425
Contact Person: Lynn M. Kirchoff
Date of Preparation: July 21, 2005
Registration Number: 1720496
Additional Registration Numbers:
C. R. Bard 2212754

5.2 Device Information

Device Name: 5 Fr SL PowerPICC™ Catheter
Trade Name: 5 Fr SL PowerPICC™ Catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: Long Term Intravascular Catheter (80 LJS)
21 CFR 880.5970, Class II
Peripherally Inserted Central Catheter
Classification Panel: General Hospital

Device Name: 6 Fr DL PowerPICC™ Catheter
Trade Name: 6 Fr DL PowerPICC™ Catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: Long Term Intravascular Catheter (80 LJS)
21 CFR 880.5970, Class II
Peripherally Inserted Central Catheter
Classification Panel: General Hospital

Device Name: Poly Per-Q-Cath® PICC (Peripherally Inserted Central Catheter)
Trade Name: Poly Per-Q-Cath® PICC Catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: Long Term Intravascular Catheter (80 LJS)
21 CFR 880.5970, Class II
Peripherally Inserted Central Catheter
Classification Panel: General Hospital

Device Name: Poly Per-Q-Cath® Triple Lumen PICC Catheter
Trade Name: Poly Per-Q-Cath® Triple Lumen PICC Catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: Long Term Intravascular Catheter (80 LJS)
21 CFR 880.5970, Class II
Central Venous Pressure Monitoring
Traditional 510(k)

<table>
<thead>
<tr>
<th>Classification Panel:</th>
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<tr>
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| Device Name:          | 6 Fr DL PowerHohn™ and PowerLine™ (Central Venous Catheter) |
| Trade Name:           | PowerHohn™ and PowerLine™ Catheters |
| Common/Usual Name:    | Central Venous Catheter |
| Classification Name:  | Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II |
| Classification Panel: | General Hospital |

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<td>K051417</td>
<td>6/30/2005</td>
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5.3 Predicate Devices

The predicate devices are:

| Device Name: | Cook Turbo-Flo® PICC Catheter |
| Trade Name:  | Cook Turbo-Flo PICC Catheter |
| Common/Usual Name: | Peripherally Inserted Central Catheter (PICC) |
| Classification Name: | Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970, Class II Peripherally Inserted Central Catheter |
| Classification Panel: | General Hospital |

| Device Name: | Cook Triple Lumen Central Venous Catheter |
| Trade Name:  | Cook Triple Lumen Central Venous Catheter |
| Common/Usual Name: | Central Venous Catheter |
| Classification Name: | Long Term Intravascular Catheter (80 LJS) 21 CFR 880.5970 Central Venous Catheter |
| Classification Panel: | General Hospital |
5.4 Device Description

Subject devices:

- Catheters range in French size from 3-5 Fr SL; 4-6 Fr DL and 6 Fr TL
- Catheter usable length ranges from 40 -60 cm.
- Catheters are open-ended catheters extruded from polyurethane material containing barium sulfate for radiopacity.
- The catheter extension legs are polyurethane extrusions. Extension legs are minimum 2.2 in. in length to promote easy application of occlusive dressings. Each extension leg has a thumb clamp.
- The luer hub base material is Isoplast polyurethane.
- The catheter has a reverse taper design
- The user is informed of the gage size in product labeling and it is printed on the luer hub.
- The catheter shaft tubing is marked with depth indicators, with “0” indicated to serve as a reference for the catheter insertion point
- Catheters are provided sterile and are packaged with legally marketed kit components that are preferred by clinicians

5.5 Intended Use of Device

The intended use is the same as the predicate devices.

The Indications for Use was expanded to include allows for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

The Indications for Use statements are as follows:

5 Fr SL and 6 Fr DL PowerPICC™

The PowerPICC™ catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the PowerPICC catheter may not exceed 300 psi. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Poly Per-Q-Cath PICC

The Poly Per-Q-Cath PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and allows for central venous pressure monitoring. For blood therapy, it is recommended that a 4 French or larger catheter be used. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Poly Per-Q-Cath Triple Lumen PICC

The Poly Per-Q-Cath® Triple Lumen PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and allows for central venous pressure monitoring.
venous pressure monitoring. For blood therapy, it is recommended that a 4 French or larger catheter be used. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

5 Fr SL and 6 Fr DL PowerHohn™ and PowerLine™

PowerHohn and PowerLine Catheters are indicated for short or long term access to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, power injection of contrast media and allow for central venous pressure monitoring. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the PowerHohn and PowerLine catheters may not exceed 300 psi. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

5.6 Technological Comparison to Predicate Devices:

The technological characteristics of the subject devices are substantially equivalent to the predicate devices in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method.

5.7 510(k) Substantial Equivalence Decision Tree:

New device compared to Marketed Device?

Yes.

Does the new device have the same indication statement as the predicates?

Yes, with expansion of indication to include allows for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Yes. The principles of operation are the same as the predicate devices.

Could the new characteristics affect safety or effectiveness?

No. There is no change in design that could affect the safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Testing was based on recognized and un-recognized standards to evaluate the device’s performance.

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was based on the below referenced standards.
Central Venous Pressure Monitoring
Traditional 510(k)

- IEC 60601-2-34:2000(E) Ed.2-Medical electrical equipment- Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
- AAMI TIR:1992- Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring

Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the subject devices are substantially equivalent to the predicate devices

5.8 Conclusion

Subject devices, except for 21 gauge catheter lumens, met the performance criteria of design verification as specified by applicable standards, test protocols and/or customer inputs. As a result the recommendation of catheter lumen of 20 gauge or larger was added to the indications for use. Based on FDA’s decision trees, the subject devices are substantially equivalent to the legally marketed predicate devices, the Cook Turbo-Flo PICC and TL Central Venous Catheter, K021557, cleared 5/30/2003.

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Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
C.R. Bard, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K051991
Trade/Device Name: POWERPICC, POLY PER-Q-CATH, 6 FR TL POLY PER-Q-CATH, POWER HOHN AND POWER LINE
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: July 21, 2005
Received: July 22, 2005

Dear Ms. Kirchoff:

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) 276-0120. 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 (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
Section 1.2

Indications for Use

510(k) Number (if known): __________

Device Name: **Single and Dual Poly Per-Q-Cath® PICC**

Indications for Use:

The Poly Per-Q-Cath PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and allows for central venous pressure monitoring. For blood therapy, it is recommended that a 4 French or larger catheter be used. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

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 of needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: 06051991 000006
Section 1.2

Indications for Use

510(k) Number (if known): __________

Device Name: 5 Fr Single Lumen and 6 Fr Dual Lumen Power PICC™

Indications for Use:

The PowerPICC™ catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the PowerPICC catheter may not exceed 300 psi. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: /KOS 1991/
Section 1.2

Indications for Use

510(k) Number (if known): __________

Device Name: 6 Fr Triple Lumen Poly Per-Q-Cath

Indications for Use:

The Poly Per-Q-Cath™ Triple Lumen PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling and allows for central venous pressure monitoring. For blood therapy, it is recommended that a 4 French or larger catheter be used. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: 9451951
Indications for Use

510(k) Number (if known): __________

Device Name: 5 Fr Single Lumen Power Hohn™ and Power Line™

Indications for Use:

PowerHohn and PowerLine Catheters are indicated for short or long term access to the central venous system. They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, power injection of contrast media and allows for central venous pressure monitoring. The maximum recommended infusion rate is 5mL/sec. The maximum pressure of power injectors used with the PowerHohn and PowerLine catheters may not exceed 300 psi. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

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 OF 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 4051941