K060341

**Section 5**
**Sherlock™ Tip Location System**
**510(k) Summary of Safety and Effectiveness**
**21 CFR 807.92(a)**

AF[illegible]2006

## 5.1 General Information

| | |
|---|---|
| Submitter Name: | Bard Access Systems, Inc. (BAS)<br>[Wholly owned Subsidiary of C. R. Bard, Inc.] |
| Address: | 5425 W. Amelia Earhart Drive<br>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: | February 9, 2006 |
| Registration Number: | 1720496 |
| Additional Registration Numbers: | |
| C.R. Bard: | 2212754 |

## 5.2 Subject Device Information

| | |
|---|---|
| Device Name: | Sherlock™ Tip Location System |
| Trade Name: | **Sherlock™ Tip Location System (TLS)** |
| Common/Usual Name: | Vascular Access Catheter Accessories |
| Classification Name: | 80 LJS – Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheter<br>21 CFR 880.5970– Class II |
| Classification Panel: | General Hospital |

## 5.3 Predicate Device Information

| | |
|---|---|
| Device Name(s): | 5 Fr Dual Lumen Groshong® nXt PICC Catheter<br>Poly Per-Q-Cath PICC |
| Trade Name(s): | **Groshong® nXt, Poly Per-Q-Cath®** |
| Common/Usual Name: | Peripherally Inserted Central Catheter (PICC) |
| Classification Name: | 80 LJS – Percutaneous, Implanted, Long-Term Intravascular Catheter<br>21 CFR 880.5970– Class II |
| Classification Panel: | General Hospital |

| Predicate Device Name | 510(k) | Clearance Date |
|---|---|---|
| 5 Fr DL Groshong® nXt PICC Catheter | K023374 | 12/18/2002 |
| Poly Per-Q-Cath® PICC | K034019 | 1/21/2004 |

| | |
|---|---|
| Device Name: | Sensor Stylet and Sensor Guidewire |
| Trade Name: | **Catheter Locator System** |
| Common/Usual Name: | Vascular Access Catheter Accessories |
| Classification Name: | 80 LJS – Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheter<br>21 CFR 880.5970– Class II |
| Classification Panel: | General Hospital |

| Predicate Device Name | 510(k) | Clearance Date |
|---|---|---|
| Sensor Stylet and Sensor Guidewire | K935380 | 2/17/1995 |

| | |
|---|---|
| Device Name: | Zortran Detector |
| Trade Name: | **Zortran Detector** |
| Common/Usual Name: | Vascular Access Catheter Accessories |
| Classification Name: | FOZ – Accessory to Percutaneous, Implanted, Intravascular Catheter<br>21 CFR 880.5970– Class II |
| Classification Panel: | General Hospital |

| Predicate Device Name | 510(k) | Clearance Date |
|---|---|---|
| Zortran Detector | K000997 | 9/7/2000 |

## 5.4 Intended Use

The intended use of the subject device is the same as the intended use of the predicate devices.

Catheter stylets provide internal reinforcement to aid in catheter placement. The Sherlock™ TLS Stylet contains passive magnets that generate a magnetic field. This field can be detected by the Sherlock™ TLS Detector to provide the placer rapid feedback on catheter tip location.

The Sherlock TLS Detector quickly locates and confirms the position of specially designed, magnet-tipped Peripherally Inserted Central Catheters (PICCS) and Central Venous Catheters (CVCs) during and after initial placement. This device may be used by appropriate caregivers in hospitals, long-term care facilities or home-care settings. The Sherlock TLS Detector provides rapid feedback to the caregiver, but was not designed to replace conventional methods of placement verification. Users are urged to confirm correct placement according to their established institutional protocol and clinical judgment.

## 5.5 Indications for Use

The Indications for Use for the Sherlock™ Tip Location System (TLS) is as follows:

Catheter stylets provide internal reinforcement to aid in catheter placement. The Sherlock™ TLS Stylet contains passive magnets that generate a magnetic field. This field can be detected by the Sherlock™ TLS Detector to provide the placer rapid feedback on catheter tip location.

## 5.6 Summary of Changes

The following are modifications made to the currently marketed predicate PICC stylet and Sensor Stylet:

- The addition of encapsulated passive magnetic material in the distal portion of the stylet to allow for detection when used with a magnetic sensor.

## 5.7 Device Description

The Sherlock Tip Location System (TLS) consists of the Sherlock TLS Detector and Sherlock TLS Stylet.

The Sherlock TLS Stylet has been developed to aid in the placement of Bard Access Systems catheters using current placement techniques. The stylets are designed to give the catheters added support and stiffness while traversing the patient's venotomy. Also, should the clinician choose to do so, the stylets have been designed to be used in conjunction with Sherlock TLS Detector to allow for rapid feedback of catheter tip placement. The information provided by the Sherlock TLS is not meant to replace conventional methods of catheter placement verification. Clinicians are urged to confirm correct catheter placement according to their established institutional protocol and clinical judgment.

## 5.8 Technological Comparison to Predicate Devices

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

## 5.9 510(k) Substantial Equivalence Decision Tree

**New device is compared to Marketed Device?**
Yes.

**Does the new device have the same indication statement and intended use as the predicate?**
Yes. However, there are minor modifications to the indication verbiage.

**Does the new device have the same technological characteristics, e.g. design, materials, etc.?**
Not in all regards. The principles of operation and basic design are the same as the predicate devices. The main changes in design are the addition of passive magnetic material encapsulated in the distal portion of the stylet.

**Could the new characteristics affect safety or effectiveness?**
Yes. The design changes may affect safety or effectiveness of the device.

**Do the new characteristics raise new types of safety and effectiveness questions?**
No. Safety and effectiveness questions are the same as for the predicate devices.

**Do accepted scientific methods exist for assessing effects of the new characteristics?**
Yes. Testing was based on FDA guidance document and standards to evaluate the devices' performance:

- *Coronary and Cerebrovascular Guidewire FDA Guidance, dated 1/95*
- *ISO 11070:1998, Sterile, single-use intravascular catheter introducers*
- *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- *AAMI/ANSI/ISO 10993-1:1997, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*

**Are performance data available to assess effects of new characteristics?**
Yes. Bench testing was based on the above referenced guidance document and standards. All test results confirm that the modified device is substantially equivalent to the predicate devices.

## 5.10 Conclusion

The Sherlock™ Tip Location System (TLS) met all the performance criteria of the tests performed and, based on FDA's decision tree, is substantially equivalent to its predicate devices covered by: K023374, K034019, K935380, and K000997.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2006

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

Re: K060341
Trade/Device Name: Sherlock™ Tip Location System (TLS)
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 9, 2006
Received: February 10, 2006

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) 276-0115. 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

**Section 4**
**Indications for Use**

510(k) Number (if known): K060341

Device Name: Sherlock™ Tip Location System (TLS)

Indications for Use:

Catheter stylets provide internal reinforcement to aid in catheter placement. The Sherlock™ TLS Stylet contains passive magnets that generate a magnetic field. This field can be detected by the Sherlock™ TLS Detector to provide the placer rapid feedback on catheter tip location.

| Prescription Use __X____ (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)

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