K063240

Section 6

NOV 2 1 2006

510(k) Summary
Sherlock™ Tip Location System (TLS) Stylet

510(k) Summary of Safety and Effectiveness Information
21 CFR 807.92

1. **Submitter Information:**

Submitter Name:	Bard Access Systems, Inc. [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-7136
Fax Number:	(801) 595 5425
Contact Person:	Lynn M. Kirchoff
Date of Preparation:	October 25, 2006

2. **Subject Device Information:**

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

3. **Predicate 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 21 CFR 880.5970– Class II
Classification Panel:	General Hospital
Premarket Notification:	K060341, concurrence date April 14, 2006

Device Name:	Sherlock™ Tip Location System (TLS) Detector
Trade Name:	**Sherlock™ Tip Location System (TLS) Detector**
Common/Usual Name:	Vascular Access Catheter Accessories
Classification Name:	80 LJS– Accessory to Percutaneous, Implanted, Long-Term Intravascular Catheter 21 CFR 880.5970– Class II
Classification Panel:	General Hospital
Premarket Notification:	K061240, concurrence date June 2, 2006

4. **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. **Intended 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.

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.

6. **Summary of Technological Characteristics in relation to Predicate Device:**

Does the new device have the same indication statement?

Yes.

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

Not in all regards. The Sherlock™ TLS Stylet has some minor differences from the predicate Sherlock™ TLS Stylet. However, the basic fundamental scientific technology of the stylet has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety and effectiveness of the device.

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

No. A failure modes and effects analysis (FMEA) of the modified device was conducted in accordance with an internal protocol based on *ISO* 14971:2000, *Medical Devices – Risk Management for Medical Devices*, to assure that risks posed by the subject device are acceptable. The analysis did not raise any new types of safety or effectiveness questions.

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*

The need for design validation was assessed and no additional validation was required. The modification to the design did not necessitate the need for additional design validation activities. There is no change in how the clinician will use the device in placement procedures, only additional clarification in the IFU for the safe and effective use of the device. Verification testing demonstrated the ability of the modified design to maintain tensile integrity under extreme kink conditions.

Biocompatibility requirements of ISO-10993, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*, and the FDA-Modified ISO 10993 Test Profile for externally communicating, blood-contacting, long-term devices, were met. No materials are used in the manufacture of the modified device that have not already been cleared for similar applications by Bard Access Systems.

Are performance data available to assess effects of new characteristics?

Yes. Verification and validation testing was performed according to protocols based on the above-referenced guidance document recommendations and standards, as well as in accordance with in-house protocols. The modified devices met the acceptance criteria for the tests performed.

Do performance data demonstrate equivalence?

Yes. Performance data demonstrated that the modified Sherlock™ TLS Stylets are substantially equivalent to the predicate devices and/ or met pre-determined acceptance criteria, and the risks associated with use of the new device were found acceptable when evaluated by FMEA.

7. Conclusion

The modified Sherlock™ TLS Stylets met predetermined performance acceptance criteria of testing performed and are substantially equivalent to the predicate Sherlock™ TLS Stylets, cleared under K060341.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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C.R. Bard, Incorporated
Ms. Lynn M. Kirchoff
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Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

NOV 2 1 2006

Re: K063240
Trade/Device Name: Sherlock™ Tip Location System (TLS)
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 25, 2006
Received: October 26, 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

Indications for Use

510(k) Number (if known): K063240

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___AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (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)

11/27/2006

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

(510(k) Number) K063240