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Soft-Cell Dual Lumen Catheter
Luer Connector Change
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

General Information:

Submitter Name:	Bard Access Systems, Inc. [Wholly owned Subsidiary of C. R. Bard, Inc.] [Distributor for Vas-Cath, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 5525
Fax Number:	(801) 595-5425
Contact Person:	Glenn Norton
Date of Preparation:	January 24, 2003

Device Information:

Device Name:	**Soft-Cell™** Dual Lumen Catheter
Trade Name:	**Soft-Cell™**
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78 MSD – Catheter, Hemodialysis, Implanted 21 CFR 876.5540(b)(1) – Class III Blood Access Device
Classification Panel:	Gastroenterology and Renal

Class III – No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(1).

Predicate Device:
(As described above)

Soft-Cell Dual Lumen Catheter	K871488

Summary of Change:

The modification to the Short-Term Dialysis Catheters is a change of material and design for the luer connectors.

Device Description:

Soft-Cell Dual Lumen Catheters as currently distributed by BAS are available in straight and precurved configurations, in multiple insertion lengths. Catheters are made of polyurethane containing barium sulfate to provide radiopacity. Colored luer connectors identify the arterial (red) and venous (blue) lumens. Each extension has an atraumatic occlusion clamp, which closes the access to the catheter. A fixed suture wing is located at the bifurcation.

Intended Use of Device:

The intended use of the Soft-Cell Dual Lumen Catheter is for use in attaining short term or long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein.

Technological Comparison to Predicate Device:

The technological characteristics of the modified Soft-Cell Dual Lumen Catheters are substantially equivalent to those of the predicate Soft-Cell catheters in terms of intended use, application, user population, design, performance, labeling, packaging, and sterilization method. The modification raises no new concerns of safety or effectiveness.

All aspects of the modified devices are identical to the predicate devices except for the luer connector hub material and design. All performance testing conducted focused on the qualification of the new connector only.

510(k) Substantial Equivalence Decision Tree:

New device is compared to Marketed Device

Yes.

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

Yes.

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

Not in all respects. The principles of operation and basic design are the same. The old blue and red luer connectors are being replaced with blue and red polycarbonate luer connectors made of a new material/design. The PC luer connectors are made of a different material, have a modified design, and use a different bonding process. The catheter remains the same in all other respects.

Could the new characteristics affect safety or effectiveness?

Yes. The new material and design of the connector and the extension tubing/connector bond integrity 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. The safety and effectiveness questions are the same for all long-term dialysis catheters.

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

Yes. Reliance on recognized standards, *ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements, ISO 594-2:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings*, and *FDA's Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*, and corresponding ISO Standards were used to evaluate the device's performance.

Biocompatibility met the 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.

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the above referenced standards and guidance document recommendations. The test results met the requirements.

Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the Soft-Cell catheters with new luer connectors are substantially equivalent to the predicate Soft-Cell catheters.

Non-Clinical Performance Data

As this change is being submitted via Abbreviated 510(k), the modification of the luer connector was done with conformance to a recognized standard:

ISO 594-2:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings.

In addition, design verification testing was conducted in conformance of FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*, to in-house protocols, and performed or evaluated based on the following FDA Guidances and recognized standards:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*
- *ISO 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements*
- *ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General Requirements*
- *AAMI/ANSI/ISO-10993-1: 1997, Biological evaluation of medical devices – Part 1: Evaluation and testing, and the FDA Modified ISO 10993 Test Profile*
- *AAMI/ANSI/ISO 11135*:1994, *Medical devices – Validation and routine control of ethylene oxide sterilization*

Only those tests applicable to the luer connection were conducted: Dimensions; Tensile strength of catheter body to hub attachment *[For this project, extension leg to hub attachment];* Leakage at hub; Catheter burst pressure (positive internal pressure).

Biocompatibility testing results met the 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.

All test results confirm the modified device to be substantially equivalent to the predicate device.

Conclusions:

Soft-Cell Dual Lumen Catheters met all the performance criteria of the testing performed and, based on FDA's decision tree, are substantially equivalent to the predicate device, the Soft-Cell Dual Lumen Catheter, K871488, concurrence date June 12, 1987.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Mr. Glenn Norton
Sr. Regulatory Affairs Specialist
Bard Access Systems, Inc.
C. R. Bard, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K030277
Trade/Device Name: Vas-Cath Soft-Cell™ Dual Lumen Catheters
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: May 29, 2003
Received: May 30, 2003

Dear Mr. Glenn Norton:

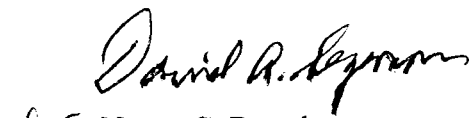
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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). You may, therefore, market the device, subject to the general controls provisions of the 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 legally 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, and 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. 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/dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030277

Section 1-B

Luer Connector Change for Soft-Cell Catheters
Abbreviated 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the following devices, Soft-Cell Dual Lumen Catheters, are indicated for the following:

> *"The* **Vas-Cath Soft-Cell** *dual lumen hemodialysis catheter is indicated for use in attaining short term or long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein."*

Signature of 510(k) Submitter: _____

Printed Name of Submitter: Glenn Norton

Date: 1-24-2003

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number _____

Division Sign-Off
Office of Device Evaluation _____

David A. Jegeris
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030277

Prescription Use ✓
(Per 21 CFR 801.109)