

JUL 30 2003

**Short-Term Dialysis 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 Names: Niagara™ Dual Lumen Catheter
Vas-Cath Flexxicon II® Dual Lumen Dialysis Catheter
Trade Names: Niagara™, Flexxicon II®
Common/Usual Name: Short-Term Hemodialysis Catheter
Classification Name: 78 MPB – Catheter, Hemodialysis, Non-implanted
21 CFR 876.5540(b)(2) – Class II
Non-Implanted Blood Access Device
Classification Panel: Gastroenterology and Renal

Predicate Devices:
(As described above)

- ◆ Niagara Dual Lumen Catheter K965178
- ◆ Vas-Cath Flexxicon II Dual Lumen Dialysis Catheter K914162

Summary of Change:

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

Device Description:

Short-Term Dialysis Catheters as currently distributed by BAS are dual lumen catheters, available in straight and precurved configurations with multiple insertion lengths. Catheters are made from soft 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, rotatable suture wing is located at the bifurcation.

Intended Use of Devices:

The intended use of the Short-Term Dialysis Catheter is attaining temporary/short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, or apheresis therapy via the jugular, subclavian, or femoral vein.

This is the same intended use as previously cleared for the Niagara Dual Lumen Catheter, K965178, concurrence date August 19, 1997, and for the Vas-Cath Flexxicon II Dual Lumen Dialysis Catheter, K914162, concurrence date July 1, 1993.

Technological Comparison to Predicate Device:

The technological characteristics of the modified Short-Term Dialysis Catheters are substantially equivalent to those of the predicate Short-Term Dialysis 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 devices are compared to Marketed Devices?**

Yes.

Do the new devices have the same indication statement as their predicates?

Yes.

Do the new devices 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 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 catheters remain 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 devices.

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 short-term dialysis catheters.

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

Yes. Reliance was placed on recognized standards to evaluate the device's performance. (See Non-Clinical Performance Data below.)

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 Short-Term Dialysis Catheters with new luer connectors are substantially equivalent to the predicate Short-Term Dialysis 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 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.

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*
- *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, which is worse case for these short-term devices.

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

Conclusions:

The Short-Term Dialysis Catheters with new luer connectors met all the performance criteria of the tests performed and, based on FDA's decision tree, are substantially equivalent to the predicate Short-Term Dialysis Catheters devices, specifically, the Niagara Dual Lumen Catheter, K965178, concurrence date August 19, 1997; and the Vas-Cath Flexxicon II Dual Lumen Dialysis Catheter, K914162, concurrence date July 1, 1993.



JUL 30 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K030268

Trade/Device Name: Niagara™ and Flexxicon® II Temporary Dual Lumen Catheters
(luer connector change)

Regulation Number: 21 CFR §876.5540

Regulation Name: Blood access device and accessories

Regulatory Class: II

Product Code: 78 MPB

Dated: May 29, 2003

Received: May 30, 2003

Dear Mr. 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 (the 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 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 Xylocaine HCL, 1%, and PVP Swabsticks, which are subject to regulation as drugs.

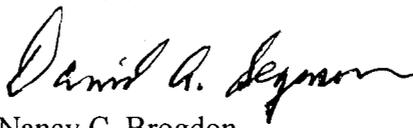
Our substantially equivalent determination does not apply to the drug component[s] of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, 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 (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/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

K030268

Short-Term Catheter Connector Change
Abbr. 510(k)

Section 1-B

Luer Connector Change for Short-Term Dialysis 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, Short-Term Hemodialysis Catheters, specifically Niagara and Flexxicon II, are indicated for the following:

"Niagara Dual Lumen Catheters are indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion and apheresis therapy via the jugular, subclavian or femoral vein."

Flexxicon II Dual Lumen Catheters are "Indicated for use in attaining temporary vascular access for hemodialysis, hemoperfusion and apheresis treatments. They are intended to be inserted in the subclavian, jugular or femoral vein, as required."

Signature of 510(k) Submitter: 

Printed Name of Submitter: Glenn Norton

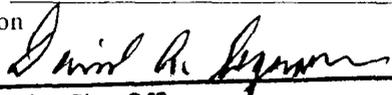
Date: 1-24-2003

*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 _____


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030268

For Prescription Use

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