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Section 6

Catheter Repair Kit with Replacement Connector

510(k) Summary

DEC 15 2006

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) 595-0700, Ext. 4903
Fax Number:	(801) 595 5425
Contact Person:	Peggy Keiffer
Date of Preparation:	November, 2006

2. Device Name:

Device Name:	Catheter Repair Kit with Replacement Connector
Trade Name:	Catheter Repair Kit
Common/Usual Name:	Catheter Repair Kit
Classification Name:	78 NFK Blood Access Device and Accessories 21 CFR 876.5540, Class II
Classification Panel:	Gastroenterology and Renal

3. Predicate Device Name:

Device Name:	Catheter Repair Kit with Replacement Connector
Trade Name:	Catheter Repair Kit
Common/Usual Name:	Catheter Repair Kit
Classification Name:	78 NFK Blood Access Device and Accessories 21 CFR 876.5540, Class II
Classification Panel:	Gastroenterology and Renal

4. Device Description

The Catheter Repair Kit with Replacement Connector is exactly the same as the predicate device.

5. Intended Use

To replace: Cracked or broken female luer lock connectors or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following catheters: Soft-Cell* Long-Term Dual Lumen Catheter, Opti-Flow* Long-Term Dual Lumen Catheter, Slim-Cath* Short-Term Dual Lumen Catheter, Vaccess* Short-Term Single Lumen Catheter, HemoStar* Long-Term Dual Lumen Catheter, Flexxicon* Short-Term Dual Lumen Catheter, Niagara* Short-Term Dual Lumen Catheter, Flexxicon* II Short-Term Dual Lumen Catheter, HemoGlide* Long-Term Dual Lumen Catheter, and HemoSplit* Long-Term Hemodialysis Catheter.

6 **Questions in the decision path and their answers follow:**

Does the new device have the same indication statement?

Yes.

Does the new device have the same intended use and may be "substantially equivalent" ?

Yes.

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

Not in all regards. The material used in the Repair Kit has a minor material formulation change. The design is the same and has the same fundamental scientific technology.

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 subject device was conducted in accordance with an internal protocol based on *ISO* 14971:2000 *Medical Devices – Application of Risk Management to Medical Devices*, to assure that risks posed by the modified 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.

Are Performance Data Available to assure effects of new Characteristics?

Yes

Do Performance Data Demonstrate Equivalence?

Yes

Conclusion:

Based on FDA's decision tree, the Catheter Repair Kit with Replacement Connector is substantially equivalent to the predicate device, Catheter Repair Kit with Replacement Connector, K030442, concurrence date July 21, 2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2006

Ms. Peggy Keiffer
Sr. Regulatory Affairs Manager
Bard Access Systems, Inc.
C. R. Bard, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K063446
Trade/Device Name: Catheter Repair Kit with Replacement Connector
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NFK
Dated: November 14, 2006
Received: November 15, 2006

Dear Ms. Keiffer:

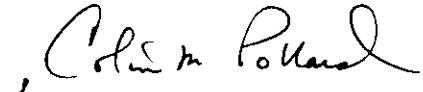
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0115. 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,



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

Enclosure

Section 1.4

Catheter Repair Kit with Replacement Connector

510(k)

Indications for Use

510(k) Number (if known): K063446

Device Name: **Catheter Repair Kit with Replacement Connector**

Indications for Use:

To replace: Cracked or broken female luer lock connectors or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following catheters: Soft-Cell* Long-Term Dual Lumen Catheter, Opti-Flow* Long-Term Dual Lumen Catheter, Slim-Cath* Short-Term Dual Lumen Catheter, Vaccess* Short-Term Single Lumen Catheter, HemoStar* Long-Term Dual Lumen Catheter, Flexxicon* Short-Term Dual Lumen Catheter, Niagara* Short-Term Dual Lumen Catheter, Flexxicon* II Short-Term Dual Lumen Catheter, HemoGlide* Long-Term Dual Lumen Catheter, and HemoSplit* Long-Term Hemodialysis Catheter.

* Soft-Cell, Opti-Flow, Slim-Cath, Vaccess, HemoStar, Flexxicon, Niagara, Flexxicon II, HemoGlide, and HemoSplit are trademarks and/or registered trademarks of C. R. Bard Inc., or an affiliate.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colleen M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063446

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