K101261

1 of 2

BARD
ACCESS SYSTEMS

JUL 29 2010

510(k) Summary

Catheter Repair Kit with Replacement Connector

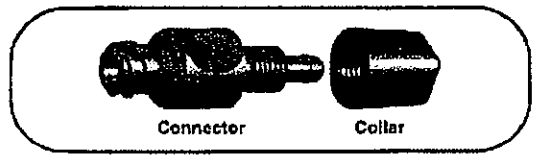
3 May 2010

General Provisions:	Submitter of 510(k) Premarket Notification:	Bard Access Systems, Inc. (BAS) [Subsidiary of C.R. Bard, Inc.] Salt Lake City, Utah 84116 Phone: (801) 522-5000, Ext. 5567 Fax: (801) 522-5425
	Contact Person:	Mark Nelson, Regulatory Affairs
	Device Trade Name:	Catheter Repair Kit with Replacement Connector
	Device Generic Name:	Catheter Repair Kit
Classification:	21 CFR §876.5540, Class II NFK– Kit, Repair, Catheter, Hemodialysis Classification Panel: Gastroenterology and Urology	
Predicate Device	Predicate Device Name:	Catheter Repair Kit with Replacement Connector K063446

Device Description

The Dialysis Catheter Repair kit is used to perform a repair of an Equistream Long-Term Dual Lumen Catheter, replacing cracked or broken luer-lock connectors, clamps, and/or damaged extension legs when a minimum of 4.5 cm of viable extension tubing exists. The repair kit components are made from Delrin.

Figure 1: The two-piece replacement connector



Device Function

The replacement connector (Figure 1) is designed to function in the same fashion as the luer connector it replaced. Dialysis is performed through the catheter by connecting the dialysis blood lines to the connectors of the dialysis catheter.

Intended Use

The intended use of the **Catheter Repair Kit with Replacement Connector** is to repair damaged external extension leg or connector on hemodialysis catheters.

Indications for Use

To replace: Cracked or broken female Luer-lock connector or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following catheters: Equistream Long-Term Dual Lumen Catheter.

K101261

2 of 2

Technological Characteristics

Technological characteristics between the subject **Catheter Repair Kit with Replacement Connector** and the predicate device remain identical. There are no changes to design, material, or chemical composition.

Verification & Validation Activities (Non-clinical Tests)

Verification and validation activities were designed and performed to demonstrate that the subject **Catheter Repair Kit with Replacement Connector** met predetermined performance specifications. Tests were performed on sterilized, finished devices. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters; March 16, 1995*
- *ISO 10555-1:1995/Amd 1:1999, Amd 2:2004; Sterile, single-use intravascular catheters, Part 1. General requirements*
- *AAMI/ANSI/ISO 10993-1:2003; Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*
- *ISO 594-2: 1998; Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment—Part 2: Lock Fittings*
- *AAMI/ANSI/ISO 11135-1:2007, Sterilization of Health Care Products—Ethylene Oxide –Part 1: Requirement for the development, Validation and Routine Control of a Sterilization Process for Medical Devices.*

The subject **Catheter Repair Kit with Replacement Connector** met all predetermined acceptance criteria derived from the above mentioned references. Design validation was conducted on the subject **Catheter Repair Kit with Replacement Connector** configuration and yielded acceptable results.

Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2007, *Medical Devices – Risk Management for Medical Devices.* No new types of safety or efficacy question were identified for the subject **Catheter Repair Kit with Replacement Connector.**

Summary of Substantial Equivalence

Comparing the intended use, indications for use, technological characteristics, and performance testing, the subject **Catheter Repair Kit with Replacement Connector** met the requirements for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to the current commercially available **Catheter Repair Kit with Replacement Connector (K063446).**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Marc Nelson
Staff Regulatory Affairs
C.R. Bard, Inc.
Bard Access Systems, Inc.
605 North 5600 West
SALT LAKE CITY UT 84116

JUL 29 2010

Re: K101261
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: May 3, 2010
Received: May 5, 2010

Dear Mr. Nelson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JUL 29 2010

510(k) Number (if known): K101261

Device Name: Catheter Repair Kit with Replacement Connector

Indications for Use:

To replace: Cracked or broken female Luer-lock connector or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following catheters: Equistream Long-Term Dual Lumen Catheter.

Prescription Use ✓ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K101261