510(k) Summary
21 CFR 807.92(a)

MAY 28 2009

Duet™ Long-Term Hemodialysis Catheter System and **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit

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. 5675 Fax: (801) 522-5425
Contact Person:	Ji Hyun Kim Regulatory Affairs Manager
Device Trade Name:	**Duet™** Long-Term Hemodialysis Catheter System **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit
Device Generic Name:	Long-Term Dialysis Catheter and accessory

Predicate Devices

Predicate Device Name	510(k)	Concurrence Date
Medcomp **Bio-Flex®** Catheter with Cuff Long-Term Hemodialysis	K981125	26 Feb,1999
Bard **HemoSplit® XK** Long-Term Hemodialysis Catheter	K033294	26 Nov, 2003

Subject Device Classification

Duet™ Catheter System:
21 CFR §876.5540(b)(1), Class III,
78 MSD–Catheter, Hemodialysis, Implanted

Duet™ Long-Term Hemodialysis Catheter System Catheter Repair Kit:
21 CFR §876.5540 Class II,
78 NFK Kit, Repair, Catheter, Hemodialysis (accessory for short-term or long-term catheter)

Performance Standards

Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Intended Use	**Duet™ Catheter System:** The **Duet™** Long-Term Hemodialysis Catheter System is recommended for use in attaining short-term and long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit: **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit is intended to replace extension leg assemblies on the **Duet™** Long-Term Hemodialysis Catheter System.
Indications for Use	**Duet™ Catheter System:** The **Duet™** Long-Term Hemodialysis Catheter System is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. The catheters may be inserted percutaneously into the internal jugular vein, subclavian or external jugular vein. **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit: To replace Extension Leg Assembly where there is a minimum of 6.0 cm of viable catheter on the **Duet™** Long-Term Hemodialysis Catheter System.
Technological Characteristics	Technological similarities between the subject **Duet™** Catheter System and repair kit and the predicate devices remain identical. There are no new questions raised regarding safety or efficacy of the **Duet™** Catheter System.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Duet™** Catheter System and **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available catheters/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2009

Ms. Ji Hyun Kim
Regulatory Affairs Manager
C.R. Bard, Inc.
Bard Access Systems, Inc.
605 North 5600 West
SALT LAKE CITY UT 84116

Re: K090528
Trade/Device Name: **Duet™** Long-Term Hemodialysis Catheter System and **Duet™** Long-Term Hemodialysis Catheter System Catheter Repair Kit
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD, NFK
Dated: February 26, 2009
Received: February 27, 2009

Dear Ms. Kim:

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 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/tray. 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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

K090528 page 1 of 2

Indications for Use Statement

510(k) Number (if known): K090528

Device Name: **Duet™** Long-Term Hemodialysis Catheter System

Indications for Use:

The **Duet™** Long-Term Hemodialysis Catheter System is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. The catheters may be inserted percutaneously into the internal jugular vein, subclavian or external jugular vein.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090528

Indications for Use Statement

Device Name: **Duet™** Long-Term Hemodialysis Catheter System
Catheter Repair Kit

Indications for Use:

To replace Extension Leg Assembly where there is a minimum of 6.0 cm of viable catheter on the **Duet™** Long-Term Hemodialysis Catheter System.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090528