K090101 Page 1 of 2

510(k) Summary
21 CFR 807.92(a)

FEB 10 2009

EQUISTREAM™ Long-Term Hemodialysis Catheter Family
Prepared January 14, 2009

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) 522-5651 Fax: (801) 522-5425
Contact Person:	Jessica Agnello Regulatory Affairs Specialist
Device Trade Name:	**EQUISTREAM™**
Device Generic Name:	Long-Term Hemodialysis Catheters

Predicate Device

Trade Name:	**HemoSplit®**
Common/Usual Name:	Long-Term Hemodialysis Catheters
Classification Name:	78 MSD–Catheter, Hemodialysis, Implanted
CFR Reference:	21 CFR §876.5540(b)(1), Class III
Classification Panel:	Gastroenterology and Urology
Premarket Notification:	See below

Predicate Device Name	510(k)	Concurrence Date
HemoSplit® Long-Term Hemodialysis Catheter	K030020	June 16, 2003

Classification

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

Performance Standards

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

Intended Use

EQUISTREAM™ catheters are recommended for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion, and apheresis treatments.

Indications for Use

The **EQUISTREAM™** long-term hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion, and apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein or femoral vein. Catheters greater than 40cm are intended for femoral vein insertion.

Technological Characteristics

Technological similarities between the subject **EQUISTREAM™** catheters and the predicate device remain identical. There are no new questions raised regarding safety or efficacy of the subject **EQUISTREAM™** catheters.

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject **EQUISTREAM™** catheters 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

FEB 10 2009

Ms. Jessica Agnello
Regulatory Affairs Specialist
C. R. Bard, Inc.
Bard Access Systems
605 North 5600 West
SALT LAKE CITY UT 84116

Re: K090101
Trade/Device Name: EQUISTREAM™ Long-Term Hemodialysis Catheter Family
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 14, 2009
Received: January 15, 2009

Dear Ms. Agnello:

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 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.

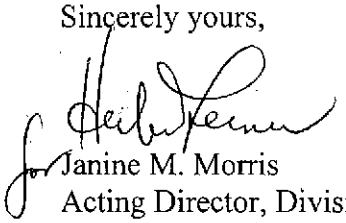
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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

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

K090101

510(k) Number (if known): K090101

Device Name: **EQUISTREAM™** Long-Term Hemodialysis Catheter Family

Indications for Use:

The **EQUISTREAM™** long-term hemodialysis catheter is indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion, and apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein or femoral vein. Catheters greater than 40cm are intended for femoral vein insertion.

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 K090101