AUG 1 2 2005

Section 6

HemoGlide® Star Series and HemoGlide® Star Series XK Long-Term Hemodialysis Catheters
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a)

General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
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Contact Person:	Michaela Rivkowich
Date of Preparation:	June 27, 2005
Registration Number:	1720496
Additional Registration Numbers:	
C.R. Bard:	2212754

Subject Device Information

Device Name:	**HemoGlide® Star** series Long-Term Hemodialysis Catheter **HemoGlide® Star** series **XK** Long-Term Hemodialysis Catheter
Trade Name:	**HemoGlide® Star** series, **HemoGlide® Star** series **XK**
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78 MSD – Catheter, Hemodialysis, Implanted 21 CFR 876.5540(b)(1) – Class III Blood Access Device
Classification Panel:	Gastroenterology and Renal

Predicate Device Information

Device Name:	**HemoSplit®** Long-Term Hemodialysis Catheter
Trade Name:	**HemoSplit®**
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78 MSD – Catheter, Hemodialysis, Implanted 21 CFR 876.5540(b)(1) – Class III Blood Access Device
Classification Panel:	Gastroenterology and Renal

Device Name:	**HemoSplit® XK** Long-Term Hemodialysis Catheter
Trade Name:	**HemoSplit® XK**
Common/Usual Name:	Long-Term Hemodialysis Catheter
Classification Name:	78 MSD – Catheter, Hemodialysis, Implanted 21 CFR 876.5540(b)(1) – Class III Blood Access Device
Classification Panel:	Gastroenterology and Renal

Predicate Device Name	510(k)	Clearance Date
HemoSplit Long-Term Hemodialysis Catheter	K030020	6/16/2003
HemoSplit XK Long-Term Hemodialysis Catheter	K033294	11/26/2003

Summary of Changes

The predicate HemoSplit and HemoSplit XK catheters have been successfully received by the clinicians. The HemoGlide Star series/HemoGlide Star series XK catheters are modifications of the HemoSplit and HemoSplit XK catheters. The main difference between the devices lies in the design of the distal lumen tips. The predicate HemoSplit/HemoSplit XK catheters are designed with a split-tip configuration whereas the subject HemoGlide Star series /HemoGlide Star series XK catheters incorporate a fixed, staggered lumen tip. A staggered lumen tip design has precedence in the market for long-term dialysis catheters; for example, BAS Opti-Flow® long-term dialysis catheters with a staggered distal lumen tip design were cleared in K010567.

This 510(k) also includes the addition of depth markings on the catheter shaft tubing and minor changes in labeling that correspond to the modified design.

Device Description

HemoGlide Star series and HemoGlide Star series XK are dual lumen long-term hemodialysis catheters. The catheters have a dual lumen, double-D cross-sectional design with a staggered distal tip. The formed venous lumen tip is designed with smooth tapered tip transitions and a guide wire passage/hole to facilitate easy over-the-wire (sheathless) placement. The molded bifurcation has an integral suture wing that is suitable for use with StatLock® securement devices. Individual arterial and venous lumen extension legs have an atraumatic occlusion clamp, which closes the access to the lumen. The clamps have integral tags with the priming volumes of the individual lumen printed on them. Red and blue color-coded luer connectors identify the arterial and venous lumens, respectively.

Intended Use

HemoGlide Star series and HemoGlide Star series XK catheters are recommended for use in attaining short-term or long-term vascular access for hemodialysis, apheresis, and hemoperfusion treatments.

Indications for Use

The **HemoGlide® Star** series and **HemoGlide® Star** series **XK** long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein.

Catheters greater than 40 cm are intended for femoral vein insertion.

Technological Comparison to Predicate Devices

The technological characteristics of the HemoGlide Star series and HemoGlide Star series XK catheters are substantially equivalent to those of the predicate HemoSplit and HemoSplit XK catheters in terms of intended use, application, user population, basic design, performance, labeling, packaging and sterilization method.

510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?

Yes.

Does the new device have the same indication statement and intended use as the predicate?

Yes.

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

Not in all regards. The principles of operation and basic design are the same as the predicate devices. The changes in design comprise of the addition of depth markings and of a modified staggered distal tip instead of a split distal tip. There is precedence in the market for a staggered tip catheter.

Could the new characteristics affect safety or effectiveness?

Yes. The design changes may affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. Safety and effectiveness questions are the same for all long-term dialysis catheters.

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

Yes. Testing was based on FDA guidance document and recognized standards to evaluate the devices' performance:

- *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 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements. Amendment 1.*
- *ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *AAMI/ANSI/ISO 11135:1994, Medical devices – Validation and routine control of ethylene oxide sterilization*

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was based on the above referenced guidance document and standards and the HemoGlide Star series and HemoGlide Star series XK catheters met the predetermined acceptance criteria.

Do performance data demonstrate equivalence?

Yes. Performance data demonstrate that the HemoGlide Star series and HemoGlide Star series XK Long-Term Hemodialysis Catheters are substantially equivalent to the predicate HemoSplit and HemoSplit XK Long-Term Hemodialysis Catheters.

Conclusion

The HemoGlide Star series and HemoGlide Star series XK Long-Term Hemodialysis Catheters met all predetermined performance acceptance and validation requirements as specified by test protocols and/or user needs and are substantially equivalent to the predicate HemoSplit Long-Term Hemodialysis Catheter, K030020, and the HemoSplit XK Long-Term Hemodialysis Catheter, K033294.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Ms. Michaela Rivkowich
Sr. Regulatory Affairs Specialist
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K051748
Trade/Device Name: HemoGlide® Star series Long-Term Hemodialysis Catheter,
HemoGlide® Star series XK Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: August 9, 2005
Received: August 10, 2005

Dear Ms. Rivkowich:

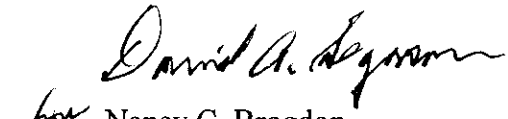
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

HemoGlide® Star series
HemoGlide® Star series XK

Section 1.2

Indications for Use

510(k) Number (if known): K051748

Device Name: HemoGlide® Star series Long-Term Hemodialysis Catheter, HemoGlide® Star series XK Long-Term Hemodialysis Catheter

Indications for Use:

The **HemoGlide®Star** series and **HemoGlide®Star** series **XK** long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein, or femoral vein.

Catheters greater than 40 cm are intended for femoral vein insertion.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ayerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051748