

NOV 26 2003

HemoSplit XK Catheter
Special 510(k)

HemoSplit XK
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

General Information:

Submitter Name: Bard Access Systems, Inc.
 [Wholly owned Subsidiary of C. R. Bard, Inc.]
 Address: 5425 W. Amelia Earhart Drive
 Salt Lake City, UT 84116
 Telephone Number: (801) 595-0700 ext. 5525
 Fax Number: (801) 595-5425
 Contact Person: Glenn Norton
 Date of Preparation: October 13, 2003

Device Information:

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

Class III – No effective date has been established for the requirement for premarket approval for the device described in paragraph (b)(1).

Predicate Device:

HemoSplit Long-Term Hemodialysis Catheter, K030020, clearance date 6/16/03

Summary of Change:

The modification to the HemoSplit Long-Term Dialysis Catheter is an increase in outer diameter to allow for greater flow at lower pressures. All other aspects of the device, HemoSplit XK, remain the same as the predicate, HemoSplit.

Device Description:

HemoSplit XK Long-Term Dialysis Catheters are dual lumen catheters available in straight configurations with multiple insertion lengths. The HemoSplit XK has a dual lumen, double-D cross-sectional design with a venous lumen tip opening molded to facilitate over-the-guide wire placement. The arterial and venous lumens are separated a maximum of 8cm proximal to the distal tip of the venous lumen, and are able to float freely in the blood stream. The molded bifurcation has an integral suture wing that is suitable for use with StatLock® securement devices. Individual arterial and venous lumen extension leg 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 of Device:

HemoSplit XK is recommended for use in attaining short-term or long-term vascular access for hemodialysis, apheresis, and hemoperfusion treatments.

Technological Comparison to Predicate Device:

The technological characteristics of the HemoSplit XK Dual Lumen Catheter are substantially equivalent to those of the predicate HemoSplit catheter 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. HemoSplit.

Does the new device have the same indication statement as the predicates?

Yes.

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

Yes. The principles of operation and basic design are the same. Only the outer diameter is changed from 14.5Fr to 16Fr.

Could the new characteristics affect safety or effectiveness?

Yes. The clinician should use medical judgement to determine when placing a larger size catheter is appropriate for the patient.

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. Reliance was placed on FDA guidance and recognized standards to evaluate the device's performance.

Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed according to the referenced standards. The test results met the requirements and were compared to the predicate device.

Do performance data demonstrate equivalence?

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

Non-Clinical Performance Data

Design verification of the modification of the HemoSplit catheter was done with conformance to in-house protocols, and performed or evaluated based on the following FDA Guidance and recognized standards:

- *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 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *AAMI/ANSI/ISO-10993-1: 1997, Biological evaluation of medical devices – Part 1: Evaluation and testing, and the FDA Modified ISO 10993 Test Profile*
- *AAMI/ANSI/ISO 11135:1994, Medical devices – Validation and routine control of ethylene oxide sterilization*

All test results confirm the modified device to be substantially equivalent to the predicate device.

Conclusions:

The HemoSplit XK Long-Term Dialysis Catheter met all the pre-determined performance criteria of the tests performed and, based on FDA's decision tree, is substantially equivalent to the predicate HemoSplit Long-Term Dialysis Catheter, K030020, concurrence date June 16, 2003.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Mr. Glen Norton
Senior Regulatory Affairs Specialist
Bard Access System, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K033294
Trade/Device Name: HemoSplit™ XK Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: November 17, 2003
Received: November 18, 2003

Dear Mr. Norton:

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.

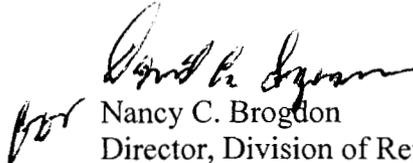
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (301) 594-4616. 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/dsma/dsmamain.html>.

Sincerely yours,



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

Enclosure

K033294

HemoSplit XK Catheter
Special 510(k)

Section 1-B

**HemoSplit™ XK Long-Term Catheter
Special 510(k)**

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the HemoSplit™ XK Long-Term Hemodialysis Catheter is indicated for the following:

"The HemoSplit™ XK long-term hemodialysis catheter is 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."

Signature of 510(k) Submitter:



Printed Name of Submitter:

Glenn Norton

Date:

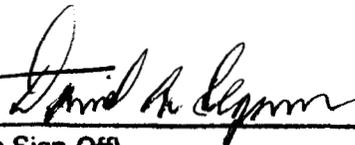
10.13.03

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number _____

Division Sign-Off _____
Office of Device Evaluation

Prescription Use 
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033294

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