

SEP 3 1998

K981994
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Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
Phone: 801-595-0700
Fax: 801-595-4969



510(K) Summary of Safety and Effectiveness

Vas-Cath Opti-Flow® Long Term Dual Lumen Hemodialysis Catheter

1. Submitter information

Submitter's Name: Bard Access Systems
Address: 5425 W. Amelia Earhart Dr.
Salt Lake City, Utah 84116
Telephone Number: 801-595-0700
Fax Number: 801-595-7156
Contact Person: Peggy Keiffer
Date of Preparation: May 29, 1998

2. Device Name: Vas-Cath Long Term Dual Lumen Hemodialysis Catheter
Trade Name: Opti-Flow®
Common/Usual Name: Hemodialysis Catheter
Classification Name: Implanted hemodialysis catheter

3. Predicate Device Name: Vas-Cath Permanent Dual Lumen Catheter
Trade name: Soft-Cell®

4. Device Description:

The Vas-Cath Opti-Flow catheter is a polyurethane catheter which allows for dialysis, hemoperfusion or apheresis. It has two clear polyurethane clamping extensions with luer connectors at the ends and atraumatic clamps. The arterial and venous extensions are identified with red and blue luer connectors. The two extensions merge into a tapered bifurcation joint or hub molded to the catheter body tubing. A removable suture wing is available for securing the catheter after initial placement. The fixed retention cuff on the shaft provides an anchoring site for tissue ingrowth during longer term placement.

The cross-section of the shaft consists of two "D"-shaped arterial and venous lumens, separated by the straight part of the "D". The venous lumen extends beyond the arterial lumen and ends with a 45 degree beveled tip. The Opti-Flow catheters are available in 19 cm, 23 cm, 27 cm, and 35 cm insertion lengths. The

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catheter is also available with a VitaCuff® antimicrobial cuff which helps to provide protection against catheter related infections and helps anchor the catheter during the initial few weeks of placement.

5. Intended Use:

The Opti-Flow Dual Lumen Catheter is indicated for use in attaining short or long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein.

6. Technological Characteristics

Characteristic	Subject Device Vas-Cath Opti-Flow Catheter	Predicate Device Vas-Cath Soft-Cell Catheter (K871488)
Shaft diameter	15 French	12.5 French
Materials	polyurethane body and extensions, PVC connectors	polyurethane body and extensions, PVC connectors
Priming Volume (arterial lumen)	19 cm: 1.8 cc 23 cm: 2.1 cc 27 cm: 2.2 cc 35 cm: 2.5 cc	12 cm: 1.3 cc 19 cm: 1.5 cc 23 cm: 1.7 cc
Priming Volume (venous lumen)	19 cm: 2.0 cc 23 cm: 2.2 cc 27 cm: 2.4 cc 35 cm: 2.7 cc	12 cm: 1.4 cc 19 cm: 1.6 cc 23 cm: 1.8 cc
Shape of arterial/venous lumens	"Double D"	"Double D"
Indications	hemodialysis, hemoperfusion, apheresis	hemodialysis, hemoperfusion, apheresis
Catheter Insertion Lengths	19cm, 23cm, 27cm, 35cm	12cm, 19cm, 23cm
Tip Characteristics	45° beveled tip	45° beveled tip
Manufacturing Process	Injection molded bifurcation onto body and extensions. Catheter is one piece.	Injection molded bifurcation onto body and extensions. Catheter is one piece.

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7. **Performance Data:**

In vitro performance data show that the Opti-Flow catheter has comparable results to the predicate catheter in regard to elongation to failure, tensile strength of molded joints, flexibility, leakage, recirculation, as well as maximum pressure and vacuum. The flow rates of the Opti-Flow catheter are greater than the Soft-Cell catheter as determined by bench testing.

In vitro test results support the labeling change of incorporating a warning against use of ointments with the catheter and the new dressing change protocol in the revised IFUs, Dressing Change Protocol, Nursing Procedure Manual and Patient Guide.

Under certain conditions, the interaction between the polyurethane tubing, PEG and moisture can lower the burst and/or radial tensile strength of the tubing, thereby increasing its susceptibility to cracking or splitting.

Since clinical personnel and/or patients cannot readily determine each ointment's formulation, the Instructions for Use instructs users to avoid all ointments and apply the dressing in such a way that the extension legs are not under the dressing.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Peggy Keiffer
Regulatory Affairs Manager
Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K981994
Vas-Cath Opti-Flow® Long-Term Dual Lumen Hemodialysis Catheter
Regulatory Class: III
21 CFR 876.5540/Product Code: 78 MSD
Dated: May 29, 1998
Received: June 8, 1998

Dear Ms. Keiffer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might

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have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains xylocaine and povidone iodine swabsticks which are subject to regulation as drugs.

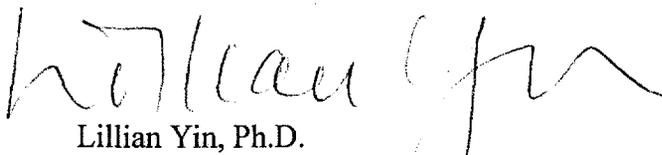
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your 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 (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal,
Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

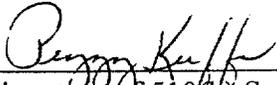
Enclosure

SECTION 1 - D

INDICATION(S) STATEMENT

I state in my capacity as Regulatory Affairs Manager of Bard Access Systems that this 510(k) premarket notification for the Opti-Flow ® Dual Lumen Catheter is indicated for the following:

The Opti-Flow Dual Lumen Catheter is indicated for use in attaining short term or long term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular or subclavian vein.



Signature of 510(k) Submitter

Peggy Keiffer
Regulatory Affairs Manager
(Printed Name of Submitter)

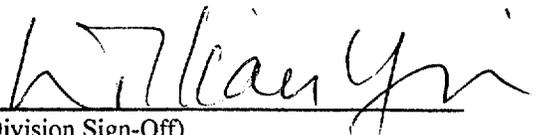
Date: 5.13.98

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

CONCURRENCE OF OFFICE OF DEVICE EVALUATION

K 981994
510(K) number

Division Sign-off, Office of Device Evaluation



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 981994

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