K974259

DEC 1 1998

Subsection II.A.

SMDA Summary of Safety and Effectiveness Information

In compliance with requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of safety and effectiveness information for this 510(k) premarket notification:

1. Predicate Device Identification

A claim of substantial equivalence of the BRMI Venous Flex II Peripheral and Intra-Operative Access Venous Return Cannulae is made to the following Baxter Research Medical, Inc. product family 510(k)s:

- K831769, Various Cardiovascular Surgical Devices [Dual Stage and Single Stage Venous Return Catheters
- K891576, FEM-Flex Femoral Access Cannulation Set

These devices were marketed prior to May 28, 1976 or have received FDA clearance to market since that date.

2. Biocompatibility Assessment

Biocompatibility testing was performed on whole product extract and/or tubesheet slices of the ethylene oxide (EtO) sterilized *test article* in accordance with testing which is based on ISO 10993 Standard, Biological Evaluation of Medical Devices.

The BRMI Venous Flex II Peripheral and Intra-Operative Access Venous Return Cannulae, PIFlex-II-xxx-V, are substantially equivalent in design and materials to BRMI FEM-FLEX™ II Femoral Cannulae, FEM II-xxx-A, marketed under K891576. The FEM II-xxx-A was used as the *test article* for this testing. The reports are summarized as follows:

- Cytotoxicity Test (MEM Elution Test) - Under conditions of the test, the test article is not cytotoxic.
- Guinea Pig Maximization Study (Magnuson/Kligman) - The test group and negative control animals showed no signs of sensitization and therefore Passes Test as a grade I sensitizer (weak).
- CFR Primary Skin Irritation Test - Under conditions of the test, the test article Passes Test in accordance with requirements of CFR Title 16 Part 1500.41.
- USP Systemic Toxicity Test - Under conditions of the test, the test article Passes Test in accordance with requirements of the USP Systemic Injection Test.
- Hemolysis Test - The test article had 0.0% Hemolysis.

3. Comparative Information

Table 1. Comparison of Specifications

Proposed Venous PIFlex II Cannulae vs. Predicate FEM-II Cannulae

BRMI PIFlex-II-xxx-V	BRMI FEM-II-xxx-A
Description: A sterile, single use, disposable cannula. Polyurethane, wire reinforced thin-wall cannula with unreinforced proximal section terminating in a barbed connector. Supplied with a polyethylene dilator. Design: BRMI will offer the cannula in the following ranges: Size: 16 - 24 Fr. Length: 12" - 20.5"	Description: A sterile, single use, disposable cannula. Polyurethane, wire reinforced thin-wall cannula with unreinforced proximal section terminating in a barbed connector. Supplied with a polyethylene dilator. Design: BRMI offers the femoral access cannula in the following: Size: 8 - 28 Fr. Length: 6" - 20.5"
Material: Body: Polyurethane Vent Cap Body: PVC Connector: PVC Dilator: Polyethylene	Material: Body: Polyurethane Vent Cap Body: PVC Connector: PVC Suture Ring: Silicone Dilator: Polyethylene Cap, Non Vent ML (T-models): ABS
Manufacturing/Inspection: SOP: Comparable to 70225 IPQA: Comparable to 80160	Manufacturing/Inspection: SOP: BRMI p/n 70225 IPQA: BRMI p/n 80160
Labeling: Comparable to p/n 61227 Exception: additional statement "care should be taken to avoid vessel perforation". This statement will be added to IFU p/n 61227. VF-II-xxx products will be used intraoperatively and in situations which peripheral cannulation (i.e. jugular, femoral, innominate) is desired for short term cardiopulmonary bypass.	Labeling: BRMI p/n 61227 . FEM-II-xxx-x are for femoral access only access.
Packaging: Individually packaged in a sealed Kwik Breathe pouch.	Packaging: Individually packaged in a sealed Kwik Breathe pouch.
Sterilization: EtO. Product is intended for single use only.	Sterilization: EtO. Product is intended for single use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1998

Mr. John W. Smith
Baxter Healthcare Corporation
6864 South 300 West
Midvale, UT 84047-1051

Re: K974259
Venous Flex II Peripheral and Intra-Operative Access Venous Return Cannulae
Regulatory Class: II (two)
Product Code: 74 DWF
Dated: September 4, 1998
Received: September 24, 1998

Dear Mr. Smith:

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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 such 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 97 4259

Device Name: BRMI Venous Flex II Peripheral and Intra-Operative Access Venous Return Cannulae, PIFlex-II-xxx-V

Indications For Use:

The BRMI Venous Flex II Peripheral and Intra-Operative Access Venous Return Cannulae, PIFlex-II-xxx-V, are intended for use in situations in which short term cardiopulmonary bypass peripheral access venous return procedures, i.e., internal jugular vein, right innominate vein, and femoral vein access, as well as the standard intra-operative access venous return procedures, i.e., right atrial appendage and right atriotomy access is desired. Venous access is left to the discretion of the physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 974259

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)