510(k) Summary, Safety and Effectiveness

JAN 22 1998

Submitter:	Baxter Healthcare Corporation CardioVascular Group Bentley Division 17511 Armstrong Avenue Irvine California 92714 USA
Contact:	Tom Humphrey Phone: 714 756 4292 Fax: 714 756 4021
Device Trade Name:	BMR™-4500 Filtered Venous Reservoir and BMR™-4500 GOLD® Filtered Venous Reservoir with Duraflo® Treatment
Common Name:	Cardiopulmonary bypass venous reservoir with cardiotomy filter.
Classification:	Class II (Reference 21 CFR 870.4400)
Predicate or Legally Marketed Device:	Bentley HSR™-4000 Venous Reservoir with Cardiotomy Autotransfusion Filter.
Date Prepared:	11/3/97

Device Description:

The BMR™-4500 GOLD® Filtered Venous Reservoir with Duraflo® Treatment is used during cardiopulmonary bypass surgery to collect, store, filter and defoam the patient's blood. All blood contacting surfaces of the device, with the exception of luer connectors, stopcock manifold and sample lines, are treated with Bentley's Duraflo® complex. This treatment is intended to enhance the blood compatibility of non-biological surfaces in the extracorporeal circuit.

Bentley's BMR™-4500 GOLD® will also be offered in a non-treated version. Designated BMR™-4500™, this device will not contain the Duraflo® complex. The indications for use for BMR™-4500™ are identical to the treated version of the device.

Bentley's BMR™-4500™ and BMR™-4500 GOLD® are intended to be used for blood flows of up to 7.0 LPM through the venous inlet, up to 5.0 LPM through the cardiotomy inlet or up to 7.0 LPM combined flow.

Indications for Use:

The BMR™-4500 Filtered Venous Reservoir is indicated for use during cardiopulmonary bypass surgery in the extracorporeal circuit to collect, store, filter and defoam the patient's blood.

The BMR™-4500 GOLD® Hard Shell Venous Reservoir with Duraflo® treatment is indicated for use during cardiopulmonary bypass surgery in the extracorporeal circuit to collect, store, filter and defoam the patient's blood. The BMR-4500 GOLD® is further intended for use when a heparin treated blood path is desired.

Technology Comparison

With exception to the addition of rotatable venous and cardiotomy inlets and supplemental luer fittings, the BMR™-4500, BMR™-4500 GOLD® and HSR™-4000 are essentially the same. The only difference between the BMR™-4500 and BMR™-4500 GOLD® is the inclusion of Bentley's Duraflo® complex in the "GOLD®" version.

Test Summary, *In-vitro*

The untreated BMR™-4500 and Duraflo® treated BMR™-4500 GOLD® Reservoirs were evaluated *in-vitro* for functional performance. The results were compared with those of the untreated HSR™-4000. The number of devices tested was selected based on AAMI guidelines (AAMI OXY-D). AAMI standards for autologous transfusion devices (AAMI AT6R-D) were also considered in the performance evaluation. The parameters under which the device was tested were considered worst case conditions.

Performance evaluation included the following tests:

- Venous and Cardiotomy Blood Damage
- Filtration Efficiency
- Venous and Cardiotomy Breakthrough Volume
- Venous and Cardiotomy Residual Volume
- Defoaming Capability
- Patency of One-Way Valve
- Heparin Leaching

The test results demonstrated no remarkable differences between the proposed vs. predicate populations.

Test Summary, *In-vivo:*

Clinical testing was not conducted. Safety and efficacy has been established via *in-vitro* analyses and historical experience with similar devices.

Test Summary, Biocompatibility:

All components of the BMR™-4500 and BMR™-4500 GOLD® were found to be biocompatible in compliance with ISO-10993-1.

Rational for Substantial Equivalence Determination

The coated and uncoated versions of Bentley's BMR™-4500 are either functionally identical or substantially equivalent to the predicate device, Bentley's HSR™-4000. The primary raw materials, principal of operation, developmental technology, functionality, intended use and labeling claims are essentially the same for all products referenced under this notification. The only notable differences between the proposed vs. predicate device are the autotransfusion function of the HSR™-4000 and addition of Bentley's Duraflo Filtered Venous Reservoir complex to the blood contacting surfaces of the GOLD® version of the device.

Bentley's Duraflo® Treatment is utilized as a biocompatible surface treatment on several devices manufactured and distributed by Baxter Healthcare corporation, Bentley Division. Numerous Duraflo treated devices have been previously "cleared" by FDA.

The results of the above referenced analyses demonstrate no remarkable differences between the proposed and predicate populations. In addition to *in-vitro* assessment, the device materials, intended use and technological characteristics of the proposed vs. predicate devices are largely identical. The test results and strong similarities in raw materials and intended use between the BMR™-4500, BMR™-4500 GOLD® and HSR™-4000, combined with Bentley's historical experience in developing similar products, provide strong rational for substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Mr. Tom Humphrey
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P.O.. Box 11150
Santa Ana, California 92711-1150

JAN 22 1998

Re: K974155
BMR™-4500 Filterted Venous Reservoir and BMR™-4500 GOLD® Filtered Venous Reservoir with Duraflo® Treatment
Regulatory Class: II (Two)
Product Code: DTN
Dated: November 3, 1997
Received: November 4, 1997

Dear Mr. Humphrey:

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 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/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

870.4400 - DTN II - Venous Reservoir

510(k) Number (if known): K974155

Device Name: BMR™-4500 and BMR™-4500 GOLD® Filtered Venous Reservoir with Duraflo® Treatment

Indications For Use:

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Concurrence of CDRH, Office OF Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974155

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)