

Bard Vascular Systems Division
C.R. Bard, Inc.
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Haverhill, MA 01832
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JUL 24 1997

An ISO 9001
Registered Division
of



510(k) SUMMARY FOR THE BARD® NO-RINSE HEMOCONCENTRATOR AND ACCESSORY KIT- HC40TS

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21CFR §807.92.

I. Submitter Information:

Name: Bard Vascular Systems Division, C.R. Bard Inc.
Address: 25 Computer Drive, Haverhill, MA 01832
Contact Person: Sandra L. Perreand
Date Summary Prepared: July 2, 1997

II. Device Name:

Proprietary Name: Bard® No-rinse Hemoconcentrator and Accessory Kit, HC40TS
Common or Usual Name: Hemoconcentrator
Classification Name: High Permeability dialyzer

III. Predicate Device(s):

- 1) Fresenius Hemoflow F40 Capillary Dialyzer
- 2) Bard® Hemoconcentrator with Tubing Set, HC70TS
- 3) Research Medical Hemoconcentrator, Biofilter™ 140

IV. Device Description:

The Bard® No-rinse Hemoconcentrator and accessory kit for hemoconcentration serve the needs of cardiopulmonary procedures. Connected to the external cardiopulmonary blood circuit, the hemoconcentrator generates ultrafiltrate with electrolyte and solute compositions similar to that of plasma water.

The Bard® No-rinse Hemoconcentrators are made of glycerin-free polysulphone membranes. The no-rinse feature provides convenience of inserting the device into the external cardiopulmonary blood circuit without the need to rinse the device.

Pre-rinsed Hemoconcentrator:

Unit Length:	29.4 cm
Unit Diameter:	2.8 cm
Membrane Surface Area:	0.7m ²
Blood Vol (Approx):	42 ml
Hollow Fiber Material:	Polysulfone
Potting Material:	Polyurethane
Filter Housing:	Polycarbonate
Port Caps:	Polyethylene
Sterilization:	Ethylene Oxide
O-Ring:	Silicone
Max Transmembrane Pressure:	600 mm Hg
Max Safe Blood Flow Rate:	500 ml/min

Accessory Kit

	ID	OD	Length
Blood Inlet tubing	1/4"	3/8"	36"
Blood Outlet tubing	1/4"	3/8"	36"
Filtrate tubing	1/4"	3/8"	36"
1/4" Male Luer Adapter	2 each		
Tubing material:	Polyvinyl chloride		

V. Indications for Use:

The indications for use for the subject device and the three predicate device's are as follows:

Indications	
Bard HC40TS hemoconcentrator	The Bard No-rinse Hemoconcentrator is intended for the relief or mitigation of overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.
Bard HC70TS hemoconcentrator	The Bard HC70TS Hemoconcentrator with Tubing Set is intended for use as an ultrafiltration system to remove excess fluid during and/or following cardiopulmonary bypass procedures where acute hemodilution has been employed.
Research Medical Biofilter 140 hemoconcentrator	The RMI BioFilter Hemoconcentrator is intended for use as an ultrafiltration device for the relief or mitigation of overhydration in patients undergoing cardiopulmonary bypass procedures and to decrease the concentration of plasma water in blood.
Fresenius Hemoflow F40 hemodialyzer	Hemoflow dialyzer Series F (High-Flux) are designed for single use in acute and chronic haemodialysis.

While the Fresenius dialyzer is indicated for use during kidney dialysis and the Bard hemoconcentrator is indicated for use during cardiopulmonary bypass procedures both device function in the same manner. Both devices are intended to remove excessive fluid and solutes

from the patients blood. The only difference between the two uses is the procedure in which it's incorporated into, ie; dialysis vs. bypass procedures.

VI. Technological Characteristics:

The Bard HC40TS is identical in terms of design and materials to the Fresenius Hemoflow F40 hemodialyzer. As summary of the technological characteristics are as follows:

	HC40TS Bard Hemoconcentrator	Fresenius Hemoflow F40 Hemoconcentrator
Housing	Polycarbonate	Polycarbonate
Potting Compound	Polyurethane	Polyurethane
Capillaries	Polysulfone	Polysulfone
O-ring	Silicone	Silicone
Port Caps	Polyethylene	Polyethylene
Unit Length	29.4 cm	29.4 cm
Unit Diameter	2.8 cm	2.8 cm
Membrane Surface Area	0.7 m ²	0.7 m ²
Max TMP	600 mmHg	600 mmHg
Max blood flow	500 ml/min	300 ml/min
Priming volume	42 ml	42 ml

VII. Performance testing

To determine the adequacy of the HC40TS as a hemoconcentrator the following performance testing was done: Cell damage, protein analysis, sieving coefficient, dynamic prime volume, ultrafiltration rate, and pressure drop. Results of this testing indicate that the HC40TS performs in a manner that is substantially equivalent to the predicate devices.



JUL 24 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandra L. Perreand
Regulatory Affairs Program Manager
Bard Vascular Systems Division
C.R. Bard, Inc.
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Haverhill, Massachusetts 01832

Re: K971180
Bard® No-Rinse Hemoconcentrator and
Accessory Kit - HC40 and HC40TS
Dated: July 2, 1997
Received: July 3, 1997
Regulatory class: III
21 CFR §876.5860/Product code: 78 KDI

Dear Ms. Perreand:

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 requirement, 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) 594-4613. 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,

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

INDICATION STATEMENT

Device Name: Bard® No-rinse Hemoconcentrator and Accessory Kit- HC40 and HC40TS

Indication for Use: The Bard® No-rinse Hemoconcentrator is intended for the relief or mitigation of overhydration in patients undergoing cardiopulmonary procedures and to increase the concentration of cells and proteins in the blood.

Robert P. Sathiyaj
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971180

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____