

AUG 6 1998

K981628

### 510(k) SUMMARY FOR THE BARD® QUANTUM™ CVR

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

A. Submitter's Information

Name: C.R. Bard, Inc., Bard Cardiopulmonary Division  
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Phone: (978) 373-1000 extension 3371  
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Contact Person: Sandra Perreand, Regulatory Affairs Manager  
Date of Preparation: April 23, 1998

B. Device Name:

Trade Name: Bard® Quantum™ SVR  
Common/Usual Name: Cardiotomy and Venous Reservoir  
Classification Name: Cardiopulmonary Bypass Blood Reservoir

C. Predicate Device Name(s):

- 1) Avacor Affinity 321 Softshell Venous Reservoir Bag, K935717
- 2) Medtronic MVR 1600 Softshell Venous Reservoir Bag, K920774

D. Device Description/Indications for Use:

The Bard® Quantum™ SVR is designed to function in an extracorporeal circuit. The flexible venous reservoir receives dynamic blood from:

- (1) venous return
- (2) suctioned blood from the cardiotomy reservoir

The venous reservoir stores this blood prior to returning it to the circuit.

E. Technological Characteristics Summary

The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (FDA 92-415, Premarket Notification 510(k): Regulatory Requirements for Medical Devices, Page 51) was utilized to make a determination of substantial equivalence as follows:

**1. Does New Device Have Same Indication Statements?**

**Yes.** The Bard® Quantum™ SVR (Bard H6440VR) has the same indications as the AVECOR Affinity Venous Reservoir Bag and the Medtronic MVR 1600 Softshell Venous Reservoir. Although the wording in the Indications for Use for all of these devices is not identical, all of these devices are indicated for use in extracorporeal systems during cardiopulmonary bypass.

**2. Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

**Yes.** The Bard H6440VR has the same technological characteristics and the same materials as at least one of the predicate devices in each category as shown in Table IV-1 or the difference is insignificant as follows.

As explained above, the Bard H6440VR has the same indications as the AVecor Affinity and the Medtronic MVR 1600 although the Bard H6440VR includes additional detail. The contraindications for the proposed device are standard phraseology and do not reflect a restriction in the use of the device. The minimum operating volume for the proposed device was statistically equivalent to both the Medtronic MVR 1600 Softshell Venous Reservoir and the AVecor Affinity VR 321 Softshell Reservoir for minimum volume to re-open the reservoir. The maximum volume of the device is simply a measure of capacity and is not a safety or efficacy concern for the device and is similar to those of the predicate devices. The materials of the device are the same as those materials used elsewhere in the device, and each material is used in one of the predicate devices in a similar location. The device was tested for biocompatibility as described in Section III and Appendix 1 and passed all testing.

**3. Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?**

**No.** Although the materials and technological characteristics are the same, differences between vendors and manufacturing techniques and the fact that neither of the predicate devices individually include all the same materials and technological characteristics as those of the proposed device necessitate bench testing to ensure equivalence.

**4. Are Performance Data Available to Assess Equivalence?**

**Yes.** The Bard H6440VR, the Avecor Affinity, and the Medtronic MVR Series were compared for performance and integrity characteristics as described in Section IV.5. Results for this testing may be found in Appendix 2.

In addition, as previously mentioned, the Bard H6440VR was subjected to biocompatibility testing (see summary in Section III and results in Appendix 1).

**5. Performance Data Demonstrate Equivalence?**

**Yes.** The performance of the Bard H6440VR was equivalent to or better than those of the predicate devices or the differences were clinically insignificant as further described in Section IV.5.

A summary of the performance and integrity testing may be found in Section IV.5. More in depth protocols and results may be found in Appendix 2. Following the summary of the performance and integrity testing is a summary of the biocompatibility testing.

**SUBSTANTIALLY EQUIVALENT DETERMINATION:**

The Bard H6440VR is substantially equivalent to the predicate devices, the Avecor Affinity and the Medtronic MVR 1600 Softshell Venous Reservoirs.



AUG 5 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sandra Perreand  
Bard Cardiopulmonary Division  
C.R. Bard, Inc.  
25 Computer Drive  
Haverhill, MA 01832

Re: K981628  
Bard® Quantum™ SVR (Softshell Venous Reservoir)  
Regulatory Class: II (Two)  
Product Code: DTN  
Dated: May 6, 1998  
Received: May 7, 1998

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 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.

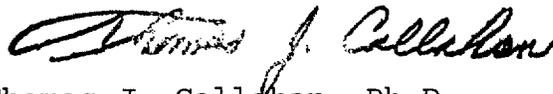
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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" (21CFR 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

**D. INDICATIONS FOR USE** K981628

**Device Name:** Bard® Quantum™ SVR (Softshell Venous Reservoir)

**Indications for Use:**

The Bard® Quantum™ SVR is designed to function in an extracorporeal circuit. The flexible venous reservoir receives dynamic blood from:

- (1) venous return
- (2) suctioned blood from the cardiotomy reservoir

The venous reservoir stores this blood prior to returning it to the circuit.

The Bard® Quantum™ SVR is designed to function for up to 6 hours in an extracorporeal circuit.

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K981628

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

Bard® Quantum™ SVR 510(k) Submission