

K960726

OCT 30 1996

Bard Vascular Systems Division
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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

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Date of Preparation: July 12, 1996

B. Device Name:

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

C. Predicate Device Name(s):

- 1) Bard® William Harvey® Cardiotomy Reservoir with MICRO Filter (H-3700) (510(k) #K902856)
- 2) Cobe HVRF®-3700 Open Venous Reservoir with Integral Cardiotomy Filter

D. Device Description/Indications for Use:

The Bard® Quantum™ CVR is designed to function in an extracorporeal circuit. The filtered cardiotomy/reservoir receives dynamic blood from:

- (1) venous return
- (2) intracardiac suction
- (3) ventricular vent devices
- (4) arterial-venous shunts

It defoams, filters and stores this blood before 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™ CVR (Bard H6770VR) has the same indications as the Cobe HVRF although the Bard H6770VR includes additional detail. The Bard H-3700 and the Bard H6770VR have the same indications for use intraoperatively; however the Bard H6770VR will not be indicated for post-operative use as the Bard H-3700 is. 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 H6770VR has the same technological characteristics and the same materials as at least one of the predicate devices or the difference is insignificant.

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

No. Although the materials and technological characteristics are the same, bench testing is necessary to ensure equivalence because of (1) differences between vendors and manufacturing techniques and (2) the fact that neither of the predicate devices individually include all the same materials and technological characteristics as those of the proposed device.

4. Are Performance Data Available to Assess Equivalence?

Yes. The Bard H6770VR, the Cobe HVRF, and the Bard H-3700 were compared for performance and integrity characteristics. In addition, the Bard H6770VR was subjected to biocompatibility testing.

5. Performance Data Demonstrate Equivalence?

Yes. The proposed device was found to be equivalent to or better than the predicated devices or differences were clinically insignificant in terms of cell damage, defoaming ability, and filtration efficiency.

The Bard H6770VR passed all tests of biocompatibility required by the International Standard ISO 10993.

SUBSTANTIALLY EQUIVALENT DETERMINATION:

The Bard H6770VR is substantially equivalent to the predicate devices, the Cobe HVRF and the Bard H-3700.