

JUN 3 1998

K980850

Bard Vascular Systems Division  
C.R. Bard, Inc.  
25 Computer Drive  
Haverhill, MA 01832  
508-373-1000

An ISO 9001  
Registered Division  
of

**BARD**

## **VI. 510(k) SUMMARY FOR THE BARD 9Fr., 40cc. REDIGUARD AND TAPERSEAL BALLOONS**

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

### **A. Submitter Information**

Submitter's Name: Bard Cardiac Assist Global Technology Center, C.R. Bard Inc.  
Address: 12 Elizabeth Drive, Chelmsford, MA 01824  
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Contact Person: Sandra L. Perreand  
Bard Cardiology  
25 Computer Drive  
Haverhill, MA 01832

Date of Preparation: February 12, 1998

### **B. Device Name**

Trade Name: Bard® 9 Fr., 40cc. RediGuard® and TaperSeal® Intra Aortic Balloon Catheters  
Common/Usual Name: Intra aortic balloon catheters  
Classification Name: Intra-Aortic System, Balloon, Intra-Aortic and Control

### **C. Predicate Device**

9Fr. 40cc ArmorGlide coated TaperSeal and RediGuard IAB catheters.

### **D. Device Description**

Each Intra Aortic Balloon catheter comes with a catheter tray and an introducer tray. The catheter tray contains: a 9Fr. 40cc IAB catheter, airway tubing w/female luer fitting, 6" pressure tubing with stopcock, a 3 way stopcock, a 60cc syringe, an optional Datascope or Arrow adaptor, 36" pressure tubing, and a male luer lock cap. The accessory tray contains; a percutaneous tearaway introducer, 8" or 11" introducer dilators, 18 gauge angiography needle, and two 150cm floppy J guidewires.

**E. Intended Use**

The device indications for use are as follows:

- Refractory left ventricular failure
- Cardiogenic or Septic shock
- Unstable refractory angina
- Impending Infarction
- Ischemia-related ventricular arrhythmias
- Weaning from Cardiopulmonary bypass
- Support and stabilization during coronary angioplasty
- Intraoperative pulsatile flow generation
- Associated mechanical complications of acute myocardial infarction
- Support and stabilization of high-risk patients undergoing general surgical procedures.

**F. Technological Characteristics Summary**

For a comparison of the two device's general characteristics see Table VI-I below.

**Table VI-I Comparison of General Characteristics**

CHARACTERISTICS	New RediGuard/TaperSeal IAB	Current RediGuard/TaperSeal IAB
Indications For Use (from the device's IFU)	The device indications for use are as follows: -Refractory left ventricular failure -Cardiogenic or Septic shock -Unstable refractory angina -Impending Infarction -Ischemia-related ventricular arrhythmias -Weaning from Cardiopulmonary bypass -Support and stabilization during coronary angioplasty -Intraoperative pulsatile flow generation -Associate to mechanical complications of acute myocardial infarction -Support and stabilization of high-risk patients undergoing general surgical procedures.	Same

**Table VI-I Comparison of General Characteristics**

<b>Contraindications</b>	-Severe aortic regurgitation -Dissecting aortic aneurysm -Severe clotting disorders -Severe aorto-iliac disease -Introduction of the IAB without the use of an introducer sheath is not recommended in patients with severe obesity, scarring of the groin, or other contra-indications to percutaneous insertion. (TS only)	Same
<b>Packaging</b>	ABS tray w/PETG lids. Double pouched in Tyvek/Mylar pouch	Same
<b>Sterilization</b>	100% EtO	Same

**G. Performance Data**

The Bard RediGuard and TaperSeal IAB catheters were subjected to biocompatibility testing as outlined in FDA's May 1, 1995 General Program memorandum- #G95-1 Attachment A, and to the FDA's current guidelines on IAB testing. All testing was successfully completed.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sandra L. Perreand  
Regulatory Affairs Manager  
Bard Cardiology-  
Cardiopulmonary GTC  
25 Computer Drive  
Haverhill, MA 01832

Re: K980850  
Bard® 9Fr., 40cc. TaperSeal® and RediGuard®  
Intra-Aortic Balloon (IAB) Modifications  
Regulatory Class: III (Three)  
Product Code: DSP  
Dated: March 3, 1998  
Received: March 5, 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 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 (Pre-market 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.

Page 2 - Ms. Sandra L. Perreand

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

510(k) Number (if known): K980850

Device Name: Bard® 9Fr., 40cc. TaperSeal® and RediGuard® Intra-Aortic Balloons

Indication for Use: -Refractory left ventricular failure,  
-Cardiogenic or septic shock,  
-Unstable refractory angina,  
-Impending infarction,  
-Ischemia related ventricular arrhythmias,  
-Weaning from cardiopulmonary bypass,  
-Support and stabilization during coronary angioplasty,  
-Intraoperative pulsatile flow generation,  
-Associated mechanical complications of acute myocardial infarction,  
-Support and stabilization of high-risk patients undergoing general surgical procedures.

(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 980850

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use