

OCT 16 1998

K 981660

VI. 510(k) SUMMARY FOR THE BARD 8Fr., 40cc. & 7Fr., 30cc SHEATHLESS INTRA-AORTIC BALLOON CATHETERS

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.

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Bard Cardiology
25 Computer Drive
Haverhill, MA 01832

Date of Preparation: May 4, 1998

B. Device Name

Trade Name: Bard® 8 Fr., 40cc. & 7Fr., 30cc 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. 30cc ArmorGlide coated TaperSeal and RediGuard IAB catheters.
DataScope IAB catheters for sheathless insertion

D. Device Description

The 8Fr. and 7Fr. IAB catheters consist of a dual lumen coaxial shaft design with either a 40cc (8Fr.) or 30cc (7Fr.) balloon attached to the distal end. The catheters all have a central lumen which serves as a guidewire introduction and pressure monitoring lumen. The central lumen also serves as the distal anchor for the balloon. The outer lumen terminates at the proximal end of the balloon. The area between the two lumens forms the gas shuttle area. Radiopaque

markers are present at both the distal tip and proximal end of the balloon. Each IAB catheter is supplied with a balloon kit and an insertion kit. The balloon kit contains the balloon catheter, airway tubing, a male luer lock cap, a 3-way stopcock, a syringe, Kontron and/or DataScope adaptor, 6" pressure tubing with a stopcock, and 36" pressure tubing. The insertion kit contains a 6" percutaneous introducer, an introducer dilator, a vessel dilator, two 150cm floppy J guidewires (0.025") and an 18 gauge angiography needle.

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 8Fr. & 7Fr. IAB | Current RediGuard/TaperSeal IAB |
|--|---|---------------------------------|
| Indications For Use (from the device's IFU) | <p>The device indications for use are as follows:</p> <ul style="list-style-type: none"> -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 |
| Contraindications | <ul style="list-style-type: none"> -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. | Same |
| Packaging | ABS tray w/PETG lids. Double pouched in Tyvek/Mylar pouch | Same |
| Sterilization | 100% EtO | Same |

G. Performance Data

The Bard 8Fr. & 7Fr. 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.

Bard® 8Fr., 40cc & 7Fr., 30cc. Sheathless Intra-Aortic Balloon Catheters 510(K)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandra L. Perreand
Regulatory Affairs Manager
Bard Cardiopulmonary & Cardiac Assist
Bard Vascular Systems Division
C.R. Bard, Inc.
25 Computer Drive
Haverhill, MA 01832

Re: K981660
Bard® 8Fr., 40cc and 7Fr., 30cc Sheathless Intra-Aortic
Balloons (IAB)
Regulatory Class: III (Three)
Product Code: DSP
Dated: August 18, 1998
Received: August 20, 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.

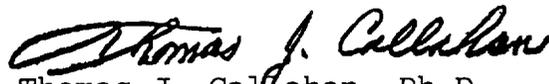
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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" (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

510(k) Number (if known): K981660

Device Name: Bard® 8Fr., 40cc & 7Fr., 30cc Sheathless Intra-Aortic Balloon Catheters

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 K981660

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)