K974247

510(k) SUMMARY

FEB 10 1998

Pursuant to Section 513(i)(3)(A) of the Federal Food, Drug and Cosmetic Act, Boston Scientific Corporation/Cardiac Assist (BSC/CA) is required to submit within this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." BSC/CA chooses to submit a summary of information regarding safety and effectiveness.

A. GENERAL INFORMATION

Submitter's Name: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Contact Person: Leo Basta
Director, Regulatory Affairs and Clinical Research

Preparation Date: 11 November 1997

B. DEVICE INFORMATION

Device Generic Name: Intra-Aortic Balloon Catheter

Device Trade Name: 40 cc Grande™

Classification Name: Percutaneous Intra-Aortic Balloon Catheter

C. PREDICATE DEVICE INFORMATION

The following devices are referenced in this premarket notification as predicate devices for the 40 cc Grande™, subject of this submission:

K971673: 40 cc SUMO for use on BSC/CA 3001, Datascope Systems 90 and 97, Kontron KAAT, St. Jude/Aries 700 and Bard H-8000.

K963187: Modified labeling of BSC/CA IAB's.

K954431: Modified Model 940 and Model 930 for use on BSC/CA 3001, Datascope Systems 90 and 97, Kontron KAAT, St. Jude/Aries 700 and Bard H-8000.

K952221: 30 cc and 40 cc Sensation™, Model 940 and Model 930 for use on Bard H-8000.

K940298: Model 940 for use on BSC/CA 3001, Datascope Systems 90 and 97, Kontron KAAT and St. Jude/Aries 700.

FDA has concurred with the substantial equivalence determination of the above referenced premarket notifications. All of these devices are currently legally marketed.

D. PROPOSED DEVICE INFORMATION

This premarket notification proposes the following changes to the current legally marketed 40 cc Grande NT™:

1. The proposed 40 cc Grande™ has a polyurethane central lumen. The polyurethane central lumen design is similar to that of the predicate Model 940 with a smaller ID and OD.

E. DEVICE DESCRIPTION

The proposed 40 cc Grande™ consists of a polyurethane blend symmetrical balloon at the distal end of a polyurethane-covered nylon shaft. The balloon is coated with a thin layer of silicone fluid. A polyurethane central lumen runs throughout the length of the catheter and terminates at the distal tip. This central lumen may be used to pass the device over a guidewire. The balloon is supplied prewrapped for insertion and supplied with a 0.025 inch extra stiff guidewire and 10 F introducer.

F. INDICATIONS FOR USE

The indications for use for the 40 cc Grande™ is **identical** to that of the currently marketed predicate devices. The indications are as follows:

- Refractory power failure.
- Cardiogenic shock.
- Unstable refractory angina.
- Impending or extending myocardial infarction (MI).
- Hemodynamically significant mechanical complications secondary to acute MI:
    - Ventricular septal defect.
    - Mitral valve regurgitation.
    - Papillary muscle rupture.
- Angiography/Angioplasty patients.
- Septal shock.

G. TECHNOLOGICAL CHARACTERISTICS

The 40 cc Grande™ is **identical** to the predicate 40 cc Grande NT™ except for the central lumen which is made of polyurethane (same as predicate Model 940 with smaller ID and OD). Test data and information demonstrates that the use of the 40 cc Grande™ is substantially equivalent to the performance of the predicate devices on the BSC/CA 3001, Datascope Systems 90 and 97, St. Jude/Aries 700, Kontron KAAT and Bard H-8000 IABP's.

H. NONCLINICAL TESTS

1. Initial Performance Testing:

To demonstrate the unwrapping and integrity of the 40 cc Grande™ post insertion and removal, test samples were tested on the BSC/CA 3001 IABP. All the proposed 40 cc Grande™ IAB's opened (unwrapped) per the Directions for Use and QA final acceptance criteria. Demonstration that the proposed 40 cc Grande™ can be inserted and removed from it's introducer twice, inserted into another introducer and passed the unwrapping test demonstrates the integrity of the device post insertion and removal.

2. Sheathed Insertion Test:

The force required to insert the 40 cc Grande™ through it's introducer, over it's guidewire at 34.8 oz was demonstrated to be substantially equivalent to the force required to insert the predicate Model 940 at 30.1 oz.

3. Sheathless Insertion Test:

The tightest restriction that the 40 cc Grande™ can pass through 100% of the time is 0.100 inch which is substantially equivalent to the predicate 40 cc Grande NT™ at 0.100 inch, the 40 cc Datascope 9.5 F Percor-Stat at 0.100 inch and the 40 cc 9 F Kontron/Arrow IAB at > 0.105 inch. This restriction is well below the 0.118 inch dilator size provided for use with the sheathless introduction technique.

4. Maximum Pumping Rate Limit Test:

The maximum pumping rate limit, defined as the maximum pumping rate at which the balloon is able to inflate and deflate fully (greater than or equal to 90% of it's nominal volume), was measured for the 40 cc Grande™ on the BSC/CA 3001 IABP. The maximum pumping rate limit was 175 bpm which is substantially equivalent to the predicate 40 cc Grande NT™ at 170 bpm and greater than the Model 940 at 140 bpm.

The proposed 40 cc Grande™ combined inflation/deflation time of 245 msec compares favorably with the combined inflation/deflation times of the predicate Model 940 at 275 msec and 40 cc Grande NT™ at 264 msec.

5. Reliability and Integrity Test:

The reliability of the 40 cc Grande™ was compared to that of the predicate 40 cc Grande NT™ and Model 940 by pumping test samples for a minimum of 3.6 million cycles. The 40 cc Grande™ test samples were all able to cycle as reliably as the predicate devices.

Dimensional inspection, visual inspection for signs of surface wear, and leak testing were performed following reliability testing. No changes in dimensions, signs of surface wear or leaks were noted.

Following reliability testing, dimensional and visual inspections and leak testing, the 40 cc Grande™ test samples were subjected to a maximum pumping rate limit test on the BSC/CA 3001. The maximum pumping rate limit post-reliability was 176 bpm which compares well with the pre-reliability value of 175 bpm. Inflate and deflate times were also found comparable post-reliability versus pre-reliability testing.

6. Trackability Test:

40 cc Grande™ test samples were inserted over their guidewire, into position, and withdrawn as a set to demonstrate that the catheters can perform with their insertion accessories. All the 40 cc Grande™ as well as the predicate devices were able to track their guidewire into place without incident. There were no catheter kinks, no guidewire kinks, nor any problems encountered inserting or removing the catheters through their introducer.

7. Transmembrane Pressure and Volume Measurement Test:

The volume of the 40 cc Grande™ at a transmembrane pressure of 50 mmHg was found to be 41.6 cc which meets the acceptance criteria of 40 cc +/- 5% and is substantially equivalent to the predicate 40 cc Grande NT™ at 41.7 cc.

At a 40 cc displacement, the 40 cc Grande™ transmembrane pressure on average will be 21.5 mmHg which meets the acceptance criteria of $\leq$ 50 mmHg and is substantially equivalent to the predicate 40 cc Grande NT™ at 26.7 mmHg.

8. Kink Resistance Test:

40 cc Grande™ test samples were manufactured, sterilized, aged to their intended shelf life of 2 years and tested for their ability to bend around the smallest radius without failure. The proposed 40 cc Grande™ with a mean kink radius of 0.51 inch was found to be less than the predicate Model 940 at 0.54 inch.

I. CLINICAL TESTS

No clinical testing was performed by Boston Scientific Corporation/Cardiac Assist in support of this premarket notification.

J. PACKAGING AND STERILIZATION

There are no changes to the packaging and sterilization of the 40 cc Grande™ as compared to the predicate devices. The catheters are placed in a plastic tray and sealed into Tyvek/Mylar pouches and sterilized using 100% Ethylene Oxide gas. Ethylene oxide gas residuals and bacterial endotoxin levels are monitored for compliance with maximum release limits.

K. POTENTIAL COMPLICATIONS

Potential complications associated with the use of intra-aortic balloon catheters, in general, appear in the device's Directions for Use and are reproduced below.

- Leg ischemia.
- Femoral, aortic or illiac dissection.
- Arterial injury.
- Renal artery occlusion.
- Arterial rupture.
- Arterial perforation.
- Hypotension.
- Distal embolization.
- Death.
- Vascular thrombosis.
- Short-term hemodynamic deterioration.
- Hemorrhage.
- Arteriovenous fistula formation.

L. CONCLUSIONS

Based on the functional and performance data and information submitted in this premarket notification, Boston Scientific Corporation/Cardiac Assist believes that the 40 cc Grande™ is substantially equivalent to the predicate devices, the 40 cc Grande NT™ and Model 940, for use on the BSC/CA 3001, Datascope Systems 90 and 97, St. Jude/Aries 700, Kontron KAAT and Bard H-8000 IABP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1998

Mr. Leo Basta
Director, Regulatory Affairs
and Clinical Research
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K974247
Cardiac Assist 40 CC Grande™ Intra-Aortic Balloon Catheter
Regulatory Class: III (three)
Product Code: 74 DSP
Dated: November 11, 1997
Received: November 12, 1997

Dear Mr. Basta:

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 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.

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

870.3535 - DSP III - Intraaortic Balloon and Control S.

510(k) Number (if known): K974247

Device Name: BOSTON SCIENTIFIC 9 FR 40cc GRANDE™ INTRA AORTIC BALLOON CATHETER

Indications For Use:

The BSC/CA IABC's are indicated for use in patients with the following conditions:

*Refractory power failure.
*Cardiogenic shock.
*Unstable refractory angina.
*Hemodynamically significant mechanical complications secondary to acute MI:
  *Ventricular septal defect.
  *Mitral valve regurgitation.
  *Papillary muscle rupture.
*Cardiac support for high risk general surgical and coronary angiography/ angioplasty patients.
*Septic shock.

The intended use of the 40 cc Grande™ remains identical to that of the currently marketed IABC's. All of the devices are intended to provide temporary circulatory support of the left ventricle through controlled mechanical displacement of a volume of blood in the aorta.

The mechanical action of the IAB catheter therapy lowers the cardiac workload by two means:

1. Systolic unloading, as noted by a reduction in the patient's systolic pressure, which provides reduced myocardial oxygen consumption (MVO_2).

2. Diastolic augmentation which provides an increase in the mean aortic pressure and leads to an improvement in systemic and coronary arterial perfusion.

Balloon pump therapy is achieved by inserting and intra-aortic balloon catheter into the descending thoracic aorta via the common femoral artery. Balloon inflation is timed to occur during diastole, beginning with the aortic valve closure. The balloon remains inflated until the onset of left ventricular ejection or systole, then rapidly deflates, reducing the aortic pressure, which in turn reduces the afterload.

(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 K974247

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)