

510(k) SUMMARY

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

Date of Preparation: 30 May 1997

B. DEVICE INFORMATION

Device Generic Name: Intra-Aortic Balloon Catheter

Device Trade Name: 30 cc SUB-9 Nitinol
40 cc SUB-9 Nitinol
30 cc SUB-9 Stainless Steel
40 cc SUB-9 Stainless Steel

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 30 cc and 40 cc SUB-9 Nitinol and Stainless Steel, subject of this submission:

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, St. Jude/Aries 700, Kontron KAAT and Bard H-8000.

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

K943919: 40 cc Sensation™ for use on Datascope System 97 and St. Jude/Aries 700.

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

K936232: Model 930 and 30 cc Sensation™ 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 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 NICATH™, Sensation™ and Models 940 and 930:

1. The catheter shaft outer diameter is 8.75 F for the proposed SUB-9 (30 cc and 40 cc volumes and Stainless Steel and Nitinol central lumens) as compared to 9 F for the predicate 30 cc and 40 cc NICATH™ and Models 940 and 930, and 9.5 F for the Sensation™.
2. The central lumen material of the proposed 30 cc and 40 cc SUB-9 Nitinol is the same as the predicate NICATH™, except that the central lumen is slightly smaller allowing a smaller folded balloon diameter.
3. The central lumen material of the proposed 30 cc and 40 cc SUB-9 Stainless Steel is the same as the predicate Sensation™, except that the central lumen is slightly smaller allowing a smaller folded balloon diameter.
4. The smaller catheter shaft of the SUB-9 design (8.75 F vs. 9 F) allows the balloons to be folded to a smaller folded balloon diameter (0.121 inch vs. 0.129 inch) as compared to the predicate devices. This smaller folded balloon diameter allows the use of a 9 F introducer with the SUB-9 design as compared to a 10 F introducer for the predicate devices.

E. DEVICE DESCRIPTION

The proposed 30 cc and 40 cc SUB-9 Stainless Steel and Nitinol consists of a polyurethane blend symmetrical balloon at the distal end of a polyurethane-covered nylon shaft. The balloons are coated with a thin layer of silicone fluid. A Nitinol central lumen runs throughout the length of the 30 cc and 40 cc SUB-9 Nitinol catheters and terminates at the distal tip. A Stainless Steel central lumen runs throughout the length of the 30 cc and 40 cc SUB-9 Stainless Steel catheters and terminates at the distal tip. Each central lumen may be used to pass the devices over their guidewire. The balloon is supplied prewrapped for insertion utilizing either a hemostasis sheath (provided in each IAB insertion kit) or sheathless.

F. INDICATIONS FOR USE

The indications for use for the proposed SUB-9 IAB's 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 30 cc and 40 cc SUB-9 Stainless Steel and Nitinol design is identical to the predicate NICATH™, uses the same balloons as the predicate NICATH™ and Models 940 and 930 and uses the same central lumen materials as the predicate NICATH™ and Sensation™. The slightly smaller catheter shaft of the SUB-9 design does not effect it's ability to perform equivalently to the predicate devices. Test data and information demonstrates that the use of the 30 cc and 40 cc SUB-9 Stainless Steel and Nitinol 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.

H. NONCLINICAL TESTS

1. Sheathed Insertion Test:

The force required to insert the SUB-9 designs (30 and 40 cc and Stainless Steel and Nitinol) was demonstrated to be substantially equivalent to the force required to insert the predicate NICATH™ and Sensation™ designs.

2. Sheathless Insertion Test:

The tightest restriction that the SUB-9 design can pass through was found to be smaller than that required for the predicate BSC/CA IAB's, the Datascope 40 cc 9.5 F Percor-Stat and the Kontron/Arrow 40 cc 9 F IAB.

3. 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 30 cc and 40 cc SUB-9. The maximum achievable pumping rate limits for the SUB-9 designs were found to be higher than that for the predicate NICATH™ and Models 940 and 930 on the BSC/CA 3001. Since the SUB-9 performed faster on the BSC/CA 3001 it will perform faster on any IABP it is labeled for use on.

4. Reliability/Integrity Test:

The reliability of the SUB-9 was found comparable to all BSC/CA predicate devices, all of which were able to cycle for at least 3.6 million cycles. The maximum pumping rate limit post-reliability was found identical to the pre-reliability rate for the 40 cc SUB-9. Inflation and deflation times post-reliability were also found comparable to pre-reliability times.

5. Aneurization and Burst Pressure Test:

The aneurization and burst pressure tests demonstrated substantially equivalent aneurization and burst pressures as compared to the predicate devices. The SUB-9 balloons will not aneurize or burst when used on the IABP's labeled for use on since the IABP's are unable to provide the volume required to aneurize the balloons then continue on to burst the balloons. The peak output pressures of all the IABP's indicated for use on is below the pressures required to aneurize and burst the balloons.

6. Transmembrane Pressure and Volume Measurement Test:

Since the balloons used on the SUB-9 are the same as the predicate Models 940 and 930 and 30 and 40 cc NICATH™, they will have the same transmembrane pressure at the same inflated volume. The volume of the 30 and 40 cc SUB-9 were found substantially equivalent to the predicate Models 940 and 930, demonstrating equal transmembrane pressures.

7. Trackability Test:

The SUB-9 test samples (30 cc and 40 cc; Stainless Steel and Nitinol) were inserted over their guidewire, into position, and withdrawn to demonstrate that the catheters can perform with their insertion accessories. All the SUB-9, as well as predicate devices, were able to track their guidewire into position in the aorta without incident. There were no catheter kinks, no guidewire kinks, nor any problems encountered inserting or removing the catheters through their introducer.

8. Kink Resistance Test:

The mean kink radius of the SUB-9 Stainless Steel and Nitinol were demonstrated to be substantially equivalent to the predicate NICATH™, Sensation™ and Models 940 and 930.

9. Initial Performance, Insertion/Removal Integrity Test:

All of the 30 cc and 40 cc SUB-9 Nitinol and Stainless Steel test samples opened as they should per the Directions for Use. The integrity of the SUB-9 design post insertion and removal was demonstrated.

Additional nonclinical tests performed for previous premarket notifications and submitted as reference information within this submission include abrasion testing and biocompatibility testing.

I. CLINICAL TESTS

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

J. STERILIZATION AND PACKAGING

There are no changes to the packaging and sterilization of the SUB-9 IAB's as compared to the predicate devices. The catheters are placed in a plastic tray and sealed into a 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 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 30 cc and 40 cc SUB-9 Nitinol and Stainless Steel are substantially equivalent to the predicate devices, NICATH™, Sensation™ and Models 940 and 930 for use on the BSC/CA 3001, Datascope Systems 90 and 97, St. Jude/Aries 700, Kontron KAAT and Bard H-8000.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

SEP - 2 1997

Re: K972113
Cardiac Assist Sub-9 Intra-Aortic Balloon Catheters
Regulatory Class: III (Three)
Product Code: 74 DSP
Dated: June 3, 1997
Received: June 5, 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.

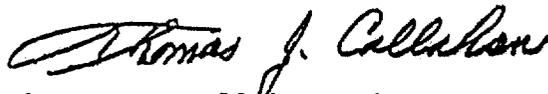
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Leo Basta

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): K972113

Device Name: 30 cc and 40 cc SUB-9

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 30 cc and 40 cc SUB-9 remain 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 consumptions (MVO₂).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thom M. ...
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K972113

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

510(k) Number: K972113

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Device Name: 30 cc and 40 cc SUB-9

Indications for Use (continued):

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 an 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.