K963187

NOV 4 1996

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: 01 August 1996

B. DEVICE INFORMATION

Device Generic Name: Intra-Aortic Balloon Catheters

Device Trade Names: Model 940
Model 930
30 cc Sensation™
40 cc Sensation™
NICATH™ 40 cc
NICATH™ 30 cc

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 sheathless insertion of BSC/CA IAB's:

K910997: Datascope 9.5 F 40 cc PERCOR STAT-DL.

K892222: Kontron 9 F 40 cc IAB for Sheathless Insertion.

These devices are currently legally marketed for sheathless insertion.

D. PROPOSED DEVICES INFORMATION

This premarket notification proposes to allow the labeling of the BSC/CA Models 940 and 930, 30 cc and 40 cc Sensation™ and NICATH™ 40 cc and 30 cc IAB's for an optional sheathless method of insertion. The sheathless insertion technique is proposed to be offerred in the Directions for Use along with the current instructions for a sheathed insertion.

E. DEVICE DESCRIPTIONS

The Models 940 and 930, 30 cc and 40 cc Sensation™ and NICATH™ 40 cc and 30 cc IAB's consist of a polyurethane blend balloon at the distal end of a polyurethane-covered nylon shaft. The balloons are coated with a thin layer of Medical Grade silicone fluid. A central lumen runs throughout the length of the catheters and terminates at the distal tip. This central lumen may be used to pass the device over a guidewire. The balloon is supplied pre-wrapped for insertion.

F. INDICATIONS FOR USE

The indications for use for the Cardiac Assist IAB's are **identical** to that of the currently marketed 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 Cardiac Assist IAB's proposed to be labeled for optional sheathless insertion are **identical** to the current legally marketed IAB's. Test data and information demonstrates that the use of the Cardiac Assist IAB's is substantially equivalent to the performance of the predicate devices (Datascope 9.5 F 40 cc PERCOR STAT-DL and Arrow 9 F 40 cc) when tested for sheathless insertion.

H. NONCLINICAL TESTS

The following tests were performed:

1. Insertion Test:

A test was designed and manufactured with an adjustable restriction to simulate a sheathless insertion. Cardiac Assist, Datascope and Arrow IAB's were inserted through the fixture at smaller and smaller increments to ascertain the tightest restriction the device could be passed through without damaging the IAB or its guidewire.

In each case the Cardiac Assist IAB's were able to be inserted through a tighter restriction without failure as compared to the Datascope and Arrow IAB's. The competitor catheters required larger openings to be able to pass through without failure.

2. Kink Resistance Test:

The Cardiac Assist, Datascope and Arrow IAB's were tested for their resistance to kinking by bending the catheter samples around a radius and measuring the smallest step on the fixture that the catheter was able to be bent around without failure. The Cardiac Assist mean radius ranged from 0.124 to 0.54 inch while the Datascope mean was 0.24 inch and the Arrow mean was 0.23 inch.

The Cardiac Assist IAB's have been demonstrated to be substantially equivalent in kink resistance to the Datascope and Arrow IAB's.

3. Trackability Test:

The Cardiac Assist, Datascope and Arrow IAB's were inserted over their guidewire into position and removed without damaging the balloon or guidewire. All of the IAB's were able to track their guidewire into proper position in the aorta without incident. There were no catheter kinks, guidewire kinks, and no problems or difficulties encountered during insertion and removal demonstrating substantial equivalence of the Cardiac Assist IAB's to Datascope and Arrow.

4. Dimensional Comparison:

A dimensional comparison was made between the Cardiac Assist and Datascope and Arrow IAB's catheter shaft diameter, folded balloon diameter, and the difference between the folded balloon diameter and catheter shaft diamter. Results indicated that the difference between the folded balloon diameter and catheter shaft diamter of the Cardiac Assist IAB's ranges from 0.009 to 0.015 inch while the Datascope is 0.009 inch and the Arrow is 0.029 inch.

The difference between the folded balloon diameter and catheter shaft diameter of the Cardiac Assist IAB's is substantially equivalent to that of the Datascope and Arrow IAB's.

I. CLINICAL TESTS

Based on conversations with FDA in April 1996, it was agreed that no formal clinical data was required to support this premarket notification.

J. STERILIZATION AND PACKAGING

There are no changes to the packaging and sterilization of the Cardiac Assist IAB's. The catheters are placed in plastic trays and sealed into Tyvek/Mylar pouches and are sterilized using 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 devices' Directions for Use and are reproduced below:

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

L. CONCLUSIONS

Based on the performance data and information submitted in this premarket notification, Boston Scientific Corporation / Cardiac Assist believes that the Cardiac Assist Models 940 and 930, 30 cc and 40 cc Sensation™ and NICATH™ 40 cc and 30 cc IAB's are substantially equivalent to the predicate devices, Datascope 9.5 F 40 cc PERCOR STAT-DL and Arrow 9 F 40 cc IAB's, with regard to sheathless insertion of the devices.