K980631

FEB 2 1999

Attachment 9
510(k) Summary

EMBOL-X, Inc.
EMBOL-X Cardioplegia Cannula/ Occluder Device
510(k) Premarket Notification

510(k) SUMMARY

I. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

EMBOL-X, Inc.
3110 Coronado Drive
Santa Clara, California 95054
Telephone: (408) 986-8301
Facsimile: (408) 986-8302

Contact Person: Donald Johnson
Vice President, Regulatory Affairs and Quality Assurance

Date Prepared: February 11, 1997

II. Name of Device and Name/Address of Sponsor

Trade name:
EMBOL-X Aortic Occlusion and Cardioplegia Cannula

EMBOL-X, Inc.
3110 Coronado Drive
Santa Clara, California 95054

III. Classification Name

Cardiopulmonary Bypass Vascular Cannula. 21 C.F.R. § 870.4210; Vascular Clamp, 21 C.F.R. § 870.4450

IV. Predicate Devices

(1) Heartport's Endoaortic Clamp (K962510)
(2) Datascope's Precluder DL Occluding Balloon (K832356)
(3) Medtronic's DLP - Aortic Root Cannula (K790565)
(4) RMI's Anteplegia Cannula (K896636)

V. Intended Use/Indications

The EMBOL-X Aortic Occlusion and Cardioplegia Cannula is intended for use during cardiopulmonary bypass (CPB) procedures to: (1) occlude the ascending aorta, (2) deliver cardioplegia solution, and (3) vent the aortic root.

VI. Device Description

The EMBOL-X Aortic Occlusion and Cardioplegia Cannula consists of a two-lumen cannula with three lines and an elastomeric balloon mounted on a 14 French tip. The first cannula lumen is used to inflate the balloon. The inflated balloon occludes the ascending aorta, partitioning the aortic root from the remainder of the arterial circulation. The balloon is expandable to occlude a range of aortic diameters. A two-way stopcock maintains the inflation and deflation of the balloon. The second cannula lumen is attached to two separate lines. The first line is used to deliver antegrade cardioplegia solution, and the second line is used for venting the aortic root. A sliding flange, located at the base of the cannula hub, adjusts to accommodate for varying aortic diameters and assists in anchoring the device during use.

VII. Principles of Operation

Prior to use, the aortic diameter is estimated in order to determine the recommended balloon inflation volume from the device labels and Instructions for Use. To prepare the device for insertion, sterile solution (saline or water) is injected into the balloon through the two-way stopcock to displace the air in the device. The air is aspirated, and the balloon is inspected for visual competency. After the air is completely aspirated, the vacuum on the balloon is maintained by closing the two-way stopcock. The clamp on the vent line is closed prior to insertion.

To insert the device, the tip is moistened and inserted in an incision in the aorta. The device is positioned in the mid-ascending aorta with the tip of the cannula directed away from the aortic root. The device is secured in position with sutures which are tied through the flange slots around the base of the cannula. The sliding flange rests against the exterior of the aorta to assist in anchoring the device. After the device has been inserted, the vent line is unclamped to allow the tubing to fill by bleedback.

Once the patient is stable on CPB and the heart is decompressed, the arterial flow is decreased, and the balloon is inflated to the recommended inflation volume to create an occlusive seal. To verify that the aorta is completely occluded, the vent line clamp is opened. If excessive bleedback is observed, the balloon volume is increased 1 cc at a time up to, but not exceeding, the maximum recommended balloon volume until complete occlusion is achieved.

Proper balloon occlusion is confirmed, then balloon volume is maintained by re turning the stopcock to the "closed" position.

After occlusion is achieved, cardioplegia solution delivery is initiated. After the CPB procedure is complete, the device is removed by reducing the arterial flow rate, deflating the balloon, loosening the sutures, withdrawing the device from the aorta, and tightening the sutures to achieve hemostasis. The arterial flow rate can then be returned to normal.

VIII. **Comparison to Predicate Devices**

The EMBOL-X Aortic Occlusion and Cardioplegia Cannula is substantially similar to currently available CPB vascular cannulae which are used to administer cardioplegia solution during CPB procedures. The EMBOL-X Device is designed with a curved tip that is surrounded by an elastomeric balloon. The balloon is deployed to partition the aortic root from the remainder of the arterial circulation and thereby prevent blood from flowing back into the surgical field. Several currently marketed devices also serve this purpose, including endoaortic clamps and other balloon-type cardioplegia catheters.

IX. Data Demonstrating Substantial Equivalence

Performance testing on the EMBOL-X Aortic Occlusion and Cardioplegia Cannula demonstrated that the device meets EMBOL-X, Inc. performance requirements for the intended clinical use of the device. Biocompatibility testing demonstrated that the materials used to fabricate the EMBOL-X Device are biocompatible and meet the requirements of FDA's guidance document, *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* (1995). Animal testing results demonstrated that the device occludes the ascending aorta and delivers cardioplegia to arrest the heart. In addition, the device is not thrombogenic, does not result in depletion of cellular components and does not damage the vessel wall.

X. Conclusion

Performance, biocompatibility and animal testing demonstrated that the EMBOL-X Aortic Occlusion and Cardioplegia Cannula is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

Ms. Alexis Ball
EMBOL-X, Inc.
645 Clyde Avenue
Mountain View, CA 94043-2208

Re: K980631
EMBOL-X Aortic Occlusion and Cardioplegia Cannulae (AOCC)
Regulatory Class: II (two)
Product Code: DXC
Dated: November 23, 1998
Received: November 24, 1998

Dear Ms. Ball:

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.

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/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

FEB 2 1999

510(k) Number (if known): K 980631

Device Name: EMBOL-X Aortic Occlusion and Cardioplegia Cannula

Indications For Use:

The EMBOL-X Aortic Occlusion and Cardioplegia Cannula is intended for use during cardiopulmonary bypass (CPB) procedures to: (1) occlude the ascending aorta, (2) deliver cardioplegia solution, and (3) vent the aortic root.

(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 K980631

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

(Optional Format 1-2-96)