K020693

SEP 5 2002

510(k) SUMMARY

SUBMITTER'S NAME:	EMBOL-X®, INC.
ADDRESS:	645 Clyde Ave, Mountain View, CA
PHONE NUMBER:	(650) 390-0280
FAX NUMBER:	(650) 390-0282
CONTACT PERSON:	Edwin Lee
DATE PREPARED:	July 3, 2002
TRADE NAME:	Aortic Cannula
COMMON NAME:	Aortic Cannula
CLASSIFICATION NAME:	Cardiopulmonary Bypass Vascular Cannula
PREDICATE DEVICE(S):	a) EMBOL-X® Introducer b) DLP® Curved Metal Tip Arterial Cannula
DEVICE DESCRIPTION:	The EMBOL-X® Aortic Cannula consist of a standard ⅜" ID wire reinforced tube body having a curved J-tip end and a flange for suture attachment. Attached to the side of the J-tip end is an Introducer port having a single lumen housing and a removable self-venting keyed snap-lock Obturator. The outer portion of the J-tip includes a radiused groove that accepts the complimentary radiused distal end of the provided Obturator. With the Obturator inserted, the Obturator provides a smooth, minimally disruptive fit along the J-tip's radiused groove. Removal of the Obturator from the Introducer port reveals a channel through which a physically compatible device may be introduced through the Introducer's hemostatic valve and along the groove of the J-tip. The Introducer port acts as an intravascular hemostasis conduit that can accommodate the introduction of intravascular devices with an exit diameter ranging from 12 FR to 14 FR in size. The Obturator is removed only when intravascular access with a device is necessary. The EMBOL-X Aortic Cannulas have an insertion diameter size of 24 FR. All models are a J-tip configuration whose tips are made from metal or plastic. The device is packaged sterile and non-pyrogenic, is single use only, and come with a separate optional use porous vent plug for cannula venting.
INTENDED USE:	The EMBOL-X Aortic Cannula is indicated for the perfusion of the ascending aorta during cardiopulmonary bypass (CPB) surgery where procedures may require the hemostatic introduction and removal of compatible intravascular devices into the vascular system. The intended use is substantially equivalent to that of the predicates.
TECHNOLOGICAL CHARACTERISTICS COMPARISON:	The EMBOL-X Aortic Cannula is technologically and substantially equivalent to the predicate devices. The EMBOL-X Aortic Cannula combines the predicate arterial cannula design with the predicate EMBOL-X Introducer design into one device. The device's principle operating functions and technological characteristics have remained unchanged.
BIOCOMPATIBILITY:	All materials used in the EMBOL-X Aortic Cannula are shown to be biocompatible.

	biocompatible.
PERFORMANCE TESTS:	In-*vitro* bench test results for joint strength, gasket seal integrity, and flow rate characteristics was substantially equivalent or better than in performance to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2002

Embol-X
c/o Mr. Edwin Lee
645 Clyde Avenue
Mountain View, CA 94043-2208

Re: K020693
Aortic Cannula
Regulation Number: 870.4210
Regulation Name: CPB Catheter, cannula, tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: June 28, 2002
Received: July 1, 2002

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: **EMBOL-X®, Inc.**

510(K) NUMBER (IF KNOWN): **K020693**

Device Name: **Aortic Cannula**

Indications For Use:

The EMBOL-X Aortic Cannula is indicated for the perfusion of the ascending aorta during cardiopulmonary bypass (CPB) surgery where procedures may require the hemostatic introduction and removal of compatible intravascular devices into the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020693

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

(Optional Format 1-2-96)