K102420

510(k) Summary

Submitter:	Edwards Lifesciences® LLC
Contact Person:	Dannette Crooms, Regulatory Affairs Associate 12050 Lone Peak Pkwy Draper, UT 84020
Date Prepared:	October 25, 2010
Trade Name:	Edwards Lifesciences® EMBOL-X® Access Device / Aortic Cannula
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass 21 CFR Part 870.4210, Product Code DWF, Class II
Predicate Device:	EMBOL-X® Aortic Cannula

OCT 2 6 2010

Device Description:

The Edwards Lifesciences EMBOL-X Access Device / Aortic Cannulae are polymeric tubes intended to provide a means of returning oxygenated blood from the oxygenator to the patient during cardiopulmonary bypass procedures. A port is included for optional insertion of the EMBOL-X filter device.

The cannulae are available in three configurations. Variants include one code with an open tip and two codes with an alternate tip hole configuration. Cannulae bodies are reinforced by means of a stainless steel wire entirely encapsulated within the wall of the cannula to minimize the potential for cannula kinking. The devices are provided sterile, they are non-pyrogenic and they are intended for single use only.

Intended Use:

The *EMBOL-X Access Device/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.

Comparative Analysis:

It has been demonstrated that the EMBOL-X Access Device / Aortic Cannula is comparable to the predicate device in intended use and other labeling, fundamental scientific technology, material types, principles of operation and functional performance evaluations.

Functional/Safety Testing:

The functional data indicate that the EMBOL-X Access Device / Aortic Cannula performs in a substantially equivalent manner when compared with the predicate device. The following functional tests were performed. All data met pre-established acceptance criteria.

- Cannula / Tip Bending - Inspection for defects after manipulation of the cannula / tip.
- Static Pressure (6hrs) - Inspection for defects after exposure to static air pressure and manipulation of the cannula/tip.
- Dynamic Pressure (6 hrs) - Inspection for defects after exposure to dynamic water flow and manipulation of the cannula/tip.

- Tip/Cannula Bond Strength – Tensile test of the tip / cannula bond.

Conclusion:

The EMBOL-X Access Device / Aortic Cannula is substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Edwards Lifesciences, LLC.
c/o Ms. Dannette Crooms
Regulatory Affairs Associate
12050 Lone Peak Parkway
Draper, UT 84020

OCT 2 6 2010

Re: K102420
EMBOL-X® Access Device/Aortic Cannula
EMBOL-X® Slim Access Device/Aortic Cannula
EMBOL-X® Glide Access Device/Aortic Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: September 24, 2010
Received: September 27, 2010

Dear Ms. Crooms:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K102420

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K102420

OCT 26 2010

Device Name: Edwards Lifesciences EMBOL-X® Access Device / Aortic Cannula

The EMBOL-X Access Device / Aortic Cannula is indicated for the perfusion of the ascending aorta during short-term (≤ 6 hours) cardiopulmonary bypass (CPB) surgery where procedures may require the hemostatic introduction and removal of compatible intravascular devices into the vascular system.

Prescription Use __x__ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Diana D. Vickney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102420