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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The following 510(k) Summary of Safety and Effectiveness information is provided in accordance with the requirements of 21 CFR §807.92 and SMDA 1990.

510(k) Number: K031946

Date Prepared: OCTOBER 20 2003

Applicant: Edwards Lifesciences LLC

Address: Research Medical Division, 6864 South 300 West, Midvale, UTAH 84047

Phone Number: 801 565 6231

Fax Number: 801 565 6177

Contact Person: Karen Jones

Trade Name: EMBOL•X® Intra-Aortic Filter

Common Name: Arterial Line Blood Filter

Classification Name: Filter, Blood, Cardiopulmonary Bypass, Arterial Line; 21 CFR §870.4260; Class II

Device Description: The EMBOL•X Intra-aortic Filter device consists of three primary components: (1) a distal heparin-coated mesh filter, mounted onto a flexible frame to form a filter basket for particulate emboli capture and retention; (2) a locking cartridge housing for attachment to the EMBOL•X Aortic Cannula side port, permitting access to the aorta and to ensure correct orientation of the filter during use; and (3) a proximal syringe-like plunger mechanism to deploy and withdraw the distal basket into and from the aorta, via the cannula, during surgery. The filter is introduced surgically into the aorta via the previously placed cannula, and particulates are captured and removed as blood passes through the filter basket. The filter may remain *in situ* for up to 60 minutes. The EMBOL•X Intra-aortic Filter utilizes conventional medical grade materials and processes, and is provided packaged, labeled, and sterile, intended for single-use.

Intended Use: The EMBOL-X Intra-aortic Filter is indicated for use with the EMBOL-X Aortic Cannula in first time, non-emergent cardiac surgery procedures to capture and remove particulate emboli from the ascending aorta and heart during and following cross clamp removal in patients aged 18 years and older.

Predicate Devices: Substantial equivalence is derived from a composite of characteristics from multiple predicate devices and detailed in K022071. The EMBOL-X Intra-aortic Filter is substantially equivalent in intended use, clinical application, principle of operation, design and materials, sterility and biocompatibility, and performance to the EMBOL-X Aortic Filter (K022071), the Medtronic Percusurge Guardwire plus temporary occlusion and aspiration system (K003992) and/or the Edwards Lifesciences AF-1025D/AF-1040D DURAFLO (heparin treated) arterial blood filter (K820044).

Technological Characteristics: The EMBOL-X Intra-aortic Filter has similar intended use, design intent, principle of operation, materials, sterility and biocompatibility, accessory requirements, and labeling as that of the predicate devices. Any noted differences between the devices (specific indications for use, method of device delivery, specific physical dimensions and geometry) do not raise new types of safety or effectiveness questions, do not introduce new technological issues, and therefore do not impact the substantial equivalence of the EMBOL-X Intra-aortic Filter.

Non-Clinical Test Results: The results of biocompatibility, in-vitro (bench), and pre-clinical (animal) tests from K022071 demonstrate that the EMBOL-X Intra-aortic filter is sterile, biocompatible, meets established internal performance specifications, and satisfies the requirements of relevant external standards and applicable FDA guidance.

Summary of Clinical Studies: Data to support the expanded indications for the EMBOL-X Intra-aortic Filter were obtained from the post market European ICEM Registry of 1645 patients. Seventeen (17) centers in Europe enrolled patients in this prospective, consecutive enrollment registry.

The European Registry patient population was compared to the Filter Arm of the US IDE Study through analyses of the Composite Safety endpoint as defined in the US IDE Study (K022071).

The patient population of the Registry included the following patients: those undergoing combination CABG and valve surgery (14.9%); those who have had prior CABG or valve surgery (4.7%); those undergoing emergent cardiac surgery (1.5%); other cardiac surgery (eg. Myxoma excision, 2.7%) and patients less than 60 years (20.7%). In addition, there were a significant number European Registry patients who met the criteria for the US IDE Clinical Study or patients undergoing first time, non-emergent coronary artery bypass grafting (CABG), aortic valve replacement or mitral valve repair or replacement only, aged 60 years and older (51.9%).

A total of 98.2% of the EMBOL-X® Aortic Filters used in the Registry captured one or more particulates.

The composite safety endpoint was comparable between the IDE Eligible Registry patients and the Filter arm of the US IDE Study. There were no increases in the composite safety endpoint between the IDE Eligible Registry patients and the Non-IDE Eligible Registry patients which were combination CABG/Valve or re-operations. Patients undergoing emergent cardiac surgery had higher event rates and patients < 60 yrs had lower event rates, both are expected given the preoperative risk factors. Further adjustments for preoperative risk factors when compared to a published, validated univariate analyses of morbidity indicated that the observed odds ratio was less than the expected. Similarly, analyses of mortality and preoperative patient risk factors indicate that the observed mortality was comparable to the expected mortality rate seen in the European Registry patients.

Conclusions Drawn From European Registry

The results from the post market European Registry demonstrate that there are no safety issues when the EMBOL-X Intra-aortic Filter is used in a broader patient population in cardiac surgery. The use of the EMBOL-X Intra-aortic Filter does not pose any additional risk to the treated patient population when compared to the US IDE Clinical Study in K022071 and the clinical data from the European Registry demonstrate that the EMBOL-X Intra-aortic Filter is compatible with cardiac surgery procedures. It was therefore concluded that the EMBOL-X Intra-aortic Filter is safe and effective when used as indicated in the instructions for use.

Summary: Review of the clinical performance of the device in a post market European Registry provides valid clinical evidence and reasonable assurance that the EMBOL-X Intra-aortic Filter is safe and effective for its intended use in a larger cardiac surgery patient population, namely first time, non-emergent cardiac surgery procedures in patients aged 18 years and older.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 3 2003

Edwards Lifesciences, LLC.
c/o Ms. Jean C. Chang
Consultant to Edwards Lifesciences
Embol-X, Inc.
6864 South 300 West
Midvale, UT 84047

Re: K031946
EMBOL-X Intra-Aortic Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: Class II (two)
Product Code: 74 DTM
Dated: October 21, 2003
Received: October 22, 2003

Dear Ms. Chang:

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.

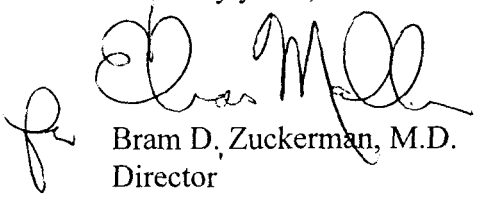
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K031946

Device Name: EMBOL-X Intra-aortic Filter

Indications For Use: The EMBOL-X Intra-aortic Filter is indicated for use with the EMBOL-X Aortic Cannula in first time, non-emergent cardiac surgery procedures to capture and remove particulate emboli from the ascending aorta and heart during and following cross clamp removal in patients aged 18 years and older.

(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 Devices

510(k) Number K031946

Prescription Use X OR
(Per 21 CFR §801.109)

Over-The-Counter Use _____