K062429

Addendum 1 510(k) Summary

SEP 27 2006

510 (k) Summary

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Submitter:	Edwards Lifesciences Research Medical, Inc.
Contact Person:	Karen Jones, Regulatory Affairs Manager 6864 South 300 West Midvale, UT 84047 801.565.6100
Date Prepared:	August 11, 2006
Trade Name:	EMBOL-X Intra-aortic Filters
Classification Name:	Class II, CFR 870.4260, DTM Filter, Blood, Cardiopulmonary Bypass, Arterial Line
Predicate Device(s):	EMBOL-X Intra-aortic Filters
Device Description:	The EMBOL-X Intra-aortic Filter is provided in a cartridge that locks into the filter lumen of the EMBOL-X Access Device/Aortic Cannula, and is inserted through the lumen by depressing a syringe like plunger mechanism. The filter then opens to fill the diameter of the ascending aorta. The filter is intended to be inserted temporarily during CPB. Filters are manufactured in 5 sizes to conform to patient anatomy.
Indications for Use:	The Embol-X Intra-aortic filter is indicated for use with the Embol-X Access Device/Aortic Cannula in first time, non emergent cardiac surgery procedures requiring aortic crossclamp, to capture and remove particulate emboli from the ascending aorta and heart in patients aged 18 years and older.
Comparative Analysis:	It has been demonstrated that the EMBOL-X Intra-Aortic Filter is comparable to the predicate device in design, intended use, materials, and principle of operation.
Functional/Safety Testing:	Not required for this change. Safety data are not new for this change.
Conclusion:	The EMBOL-X Intra-Aortic Filter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2006

Edwards Lifesciences Research Medical
c/o Ms. Karen Jones
Regulatory Affairs Manager
6864 South 300 West
Midvale, UT 84047

Re: K062429
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: DTM
Dated: September 15, 2006
Received: September 18, 2006

Dear Ms. Jones:

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

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

Enclosure

510(k) Number (if known): K062429

Device Name: *EMBOL-X Intra Aortic Filter*

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of **Cardiovascular Devices**

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