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: K022071

FEB 1 4 2003

Date Prepared: February 13 2003

Applicant: EMBOL•X, Inc.

Address: 645 Clyde Avenue, Mountain View, CA 94043

Phone Number: 650/390-0280

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Contact Person: Jean Chang

Trade Name: EMBOL•X® 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 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 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 Aortic Filter is indicated for use with the EMBOL-X Aortic Cannula in cardiac surgery procedures to capture and remove particulate emboli from the ascending aorta and heart during and following cross clamp removal in patients aged 60 years and older undergoing first time non-emergent CABG or isolated aortic or mitral valve repair/replacement.

Predicate Devices: Substantial equivalence is derived from a composite of characteristics from multiple predicate devices. The EMBOL•X Aortic Filter is substantially equivalent in intended use, clinical application, principle of operation, design and materials, sterility and biocompatibility, and performance to 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 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 Aortic Filter.

Non-Clinical Test Results: The results of biocompatibility, in-vitro (bench), and pre-clinical (animal) tests demonstrate that the EMBOL•X 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 EMBOL•X Aortic Filter (and associated EMBOL•X Aortic Cannula) were obtained from the EMBOL•X ICEM 2000 trial. The purpose of this prospective, multi-center, 1:1 randomized, controlled equivalency study was to demonstrate the safety and effectiveness of the EMBOL•X Aortic Filter (and the associated EMBOL•X Aortic Cannula) in capturing particulate emboli during first-time non-emergent coronary artery bypass graft (CABG) or aortic/mitral valve repair/replacement procedures utilizing cardiopulmonary bypass. This study was conducted at 22 sites within the United States and Canada, and was comprised of 1289 patients, of which 645 were randomized to the EMBOL•X Aortic Filter, and 644 were randomized to control. An independent Clinical Events Committee (CEC) adjudicated the major clinical endpoints and events.

Summary of Clinical Studies (continued):

The primary safety measure was a composite endpoint comprised of the following post-operative clinical events, measured from the time of randomization (the operation) through hospital discharge or 30 days, whichever occurred first: Neurologic deficit (mild and severe); Renal insufficiency (with and without dialysis); Gastrointestinal (GI) complications; Perioperative Myocardial Infarction (MI); Limb-threatening peripheral embolism (Limb Ischemia); and Death. The primary effectiveness endpoint was the capture of particulate emboli by the filter (Treatment arm only) in at least 75% of the filtered patients, with particulate debris visually confirmed by light microscopy.

The patient population of this study was limited to 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. Of the 1289 patients studied, 927 (71.9%) were male, and 1042 (80.8%) were 65 years of age or older; 65 (5.0%) had a LVEF < 30%, and 388 (30.1%) had a prior MI. None of the demographic or medical history differences between the randomized groups achieved statistical significance ($p<0.05$).

18 of 22 enrolling centers performed peri-procedural ultrasound imaging (TEE or EPI), resulting in an analysis of a subset (910, or 70.6%) of the total enrolled patients.

The primary safety endpoint was met, with the EMBOL•X Aortic Filter arm composite event rate statistically equivalent to that of standard treatment (17.1% vs. 18.9%, $p<0.001$). In addition, differences in the stratified events between the randomized groups did not achieve statistical significance ($p<0.05$). The primary effectiveness endpoint was also met, with particulate capture demonstrated in 96.8% of all filters analyzed ($p<0.001$).

The following tables summarize the results of the ICEM trial.

Table 1.

Major Adverse Events [Number (%)]

Event	Treatment (N=645)	Control (N=644)	P-Value
Death	10 (1.6)	11 (1.7)	0.82
Neurologic deficit (Stroke/TIA)	18 (2.8)	18 (2.8)	1.00
Renal insufficiency (RI)	40 (6.2)	52 (8.1)	0.19
RI (w/o dialysis)	33 (5.1)	43 (6.7)	0.23
RI (dialysis)	7 (1.1)	9 (1.4)	0.61
Myocardial infarction (MI)	67 (10.4)	64 (9.9)	0.79
Q Wave MI	21 (3.3)	18 (2.8)	0.63
CK-MB Elevation	46 (7.1)	46 (7.1)	0.99
Gastrointestinal complications (GI)	5 (0.8)	5 (0.8)	1.00
Limb ischemia	3 (0.5)	3 (0.5)	1.00
Any event	110 (17.1)	122 (18.9)	0.38

Numbers are for all randomized patients

Death: Death for any cause

Stroke: Central neurologic deficit persisting for > 24 hours

Transient neurologic deficit (TIA): An ischemic event of the central nervous system that causes a neurologic deficit persisting for < 24 hours

Renal insufficiency: Increase of serum creatinine to > 2.0 mg/dl or a 50% or greater increase over abnormal baseline prior to procedure

Renal insufficiency (dialysis): The new requirement for dialysis

Q-Wave MI: New pathological Q-Waves in 2 or more contiguous leads

Non Q-Wave MI: CPK > 5x normal and CK-MB > 5x above the upper limit of normal for the institution, in the absence of new Q-Waves

Gastro-Intestinal Complications: include GI bleeding requiring transfusion; Pancreatitis with abnormal amylase/lipase requiring NG suction therapy; Cholecystitis requiring cholecystectomy or drainage; Mesenteric ischemia requiring exploration

Limb-threatening Peripheral Embolism: Acute onset of diminished pulse, altered pallor (discoloration, either hypo- or hyper-), and pain as evidence of limb-threatening peripheral ischemia

Table 2.

Echocardiographically Evident Endothelial Disruptions Observed through Imaging

Treatment n/N (%)	Control n/N (%)	P-Value
42/456 (9.2)	9/454 (2.0)	< 0.001

Table 3.

Composite Endpoint Events Stratified by Echocardiographically Evident Endothelial Disruptions Observed through Imaging

Arm	Events in Patients With Endothelial Disruption n/N (%)	Events in Patients Without Endothelial Disruption n/N (%)	P-Value
Treatment	2/42 (4.8)	74/414 (17.9)	0.03
Control	1/9 (11.1)	81/445 (18.2)	1.0

Table 4. Particulate Capture Effectiveness

Attribute	Result
Number EMBOL•X Filters Deployed	618
Number (%) Filters Which Captured ≥ 1 Particle	598 (96.8%)
Lower 95% Confidence Bound on Percent of Filters Which Captured ≥ 1 Particle	95.3%

Conclusions drawn from Study

The results from the clinical investigation demonstrate that the EMBOL•X Aortic Filter, when used in patients undergoing first time, non-emergent Coronary Artery Bypass Grafting (CABG), aortic valve replacement or mitral valve repair or replacement, does not pose any additional risk to the treated patient population when compared to that of the current standard treatment of no filtration, and the Aortic Filter was effective in capturing particulates. The data demonstrate that the EMBOL•X Aortic Filter is compatible with conventional CPB procedures. It was therefore concluded that the EMBOL•X Aortic Filter is safe and effective when used as indicated in the Instructions for Use.

Summary: Review of the device *in vivo* and *in vitro* pre-clinical studies, combined with the results of the clinical investigation, provides valid scientific evidence and reasonable assurance that the EMBOL•X Aortic Filter is safe and effective for its intended use. Comparison of the product attributes supports the conclusion that the device is substantially equivalent to the commercially marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2003

EMBOL-X, Inc.
c/o Ms. Jean Chang
Chief Operating Officer and Executive Vice President
645 Clyde Ave.
Mountain View, CA 94043-2208

Re: K022071
Trade Name: EMBOL-X® Aortic Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Filter, Blood, Cardiopulmonary Bypass, Arterial Line
Regulatory Class: Class II (two)
Product Code: DTM
Dated: November 22, 2002
Received: November 25, 2002

Dear Ms. Chang:

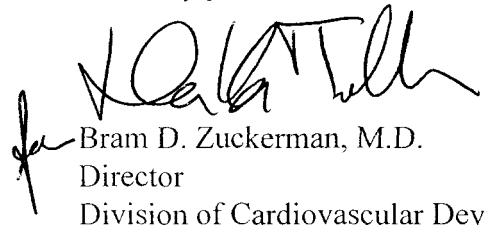
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), please contact the Office of Compliance at (301) 594-4646. 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/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): K022071

Device Name: EMBOL•X Aortic Filter

Indications For Use: The EMBOL-X Aortic Filter is indicated for use with the EMBOL-X Aortic Cannula in cardiac surgery procedures to capture and remove particulate emboli from the ascending aorta and heart during and following cross clamp removal in patients aged 60 years and older undergoing first time non-emergent CABG or isolated aortic or mitral valve repair/replacement.

(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 K022071

Prescription Use X
(Per 21 CFR §801.109)

OR Over-The-Counter Use _____