APPENDIX I 510(k) Summary

A. Submitter Information

Daun Putnam, Regulatory Specialist
Edwards Lifesciences
One Edwards Way
Irvine, CA 92614-5686
Phone Number: (949) 250-2217
Fax Number: (949) 250-3579
Email address: daun_putnam@edwards.com

B. Device Information

1. Trade Name:

   Edwards Lifespan Reinforced Expanded PTFE Vascular Graft

   Edwards Lifespan Reinforced Expanded PTFE Externally Supported Vascular Grafts

   Edwards Lifespan Reinforced Expanded PTFE Stepped Vascular Graft

2. Common or Usual Name:

   Vascular Graft Prosthesis

3. Device Classification and Classification Name:

   Class II (DSY, 21 CFR 870.3460, vascular graft of 6 mm diameter or greater)

   Class II (DYF, 21 CFR 870.3450, vascular graft of less than 6 mm diameter)

4. Predicate Device Identification:

   Baxter Reinforced Expanded PTFE Vascular Graft (K933590)

   Baxter Reinforced Expanded PTFE Stepped Vascular Graft (K944844)

   Baxter Reinforced Expanded PTFE Externally Supported Vascular Grafts (K944858)

5. Device Description:

   The subject devices are vascular grafts consisting of a base tube of expanded PTFE that is wrapped with PTFE tape for better strength. Externally supported grafts have a monofilament of PTFE wrapped over the tape for added crush and kink resistance. The stepped grafts have a 4 mm diameter end with a step up to the 7 mm diameter end. All models of the graft have a printed black orientation line consisting of "Edwards Lifesciences" printed repeatedly along the length of the graft.

6. Intended Use:

   - The Edwards Lifespan ePTFE Vascular Grafts are indicated for use as a vascular prosthesis only. The grafts are intended for bypass or reconstruction of diseased or occluded blood vessels, or for arteriovenous shunts for blood access.

   - The physician must evaluate each alternative method of treatment, discuss the risks and benefits with each patient, and decide whether to use a prosthetic vascular graft based upon all available factors.

   - Grafts with removable external monofilament support over the length of the graft are used in bypass or reconstruction of diseased

or occluded blood vessels, where compression or kinking could jeopardize patency.

- Grafts with external monofilament supporting the middle of the graft may be used for the creation of an arteriovenous shunt for blood access; however, the graft must not be cannulated in the area of the external monofilament support.

- Stepped grafts are used for the creation of arteriovenous shunts for blood access. Stepped configurations may reduce the risk of steal syndrome and high cardiac output.

7. Technological Comparison of Subject Device to Predicate Device:

   The physical characteristics, the intended use and the mode of use of the subject device are very similar to the predicate devices.

8. Summary of Non-Clinical Tests and Conclusions:

   In vitro performance testing and biocompatibility evaluations were conducted on the subject devices. Test specific to vascular grafts included burst pressure, suture retention, internodal distance and water entry pressure. Additionally, the printing was checked for legibility at the time of printing and after sterilization and aging. All testing demonstrated that the subject device met its acceptance criteria.

9. Summary of Clinical Tests and Conclusions:

   No clinical tests specific to the subject device have been conducted. The subject devices are expected to have a risk to benefit ratio similar to the predicate devices.

C. Submitter's Signature and Date of Summary Preparation

Daun S. Putnam 9/15/03

Daun Putnam
Regulatory Specialist

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Edwards Lifesciences, LLC.
c/o Ms. Daun Putnam
One Edwards Way
Irvine, CA 92614

Re: K032900
Lifespan Reinforced ePTFE Straight Vascular Graft
Regulation Number: 21 CFR 807.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: September 15, 2003
Received: September 17, 2003

Dear Ms. Putnam:

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) 594-4648. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K032900

Device Name: Lifespan™ Reinforced ePTFE Vascular grafts

Indications For Use:

The Edwards Lifespan ePTFE Vascular Grafts are indicated for use as a vascular prosthesis only. The grafts are intended for bypass or reconstruction of diseased or occluded blood vessels, or for arteriovenous shunts for blood access.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-off)
Division of Cardiovascular Devices

510(K) Number K032900 (SM. K)