510(k) Summary

SEP 0 2 2005

1. Submitter's Name and Address:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

2. Contact:

Kevin Drisko
Sr. Regulatory Manager
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
Phone: 949-250-2416
FAX: 949-250-3630
E-Mail: kevin_drisko@edwards.com

3. Date Prepared:

August 5, 2005

4. Device Trade Name:

Edwards Peripheral Dilation Catheter

5. Device Common Name:

Peripheral Dilation Catheter

6. Device Classification Name:

Catheter, percutaneous (DQY), Class II

7. Predicate Devices:

Edwards Peripheral Dilation Catheter (K032587) and
LifeStent Turbo Biliary Stent System (K050627)

510(k) Summary (continued)

8. Device Description:

The Edwards Peripheral Dilation Catheter is an over-the-wire catheter with a flexible distal portion for maneuvering through regions of the peripheral vasculature. A balloon is mounted on the distal end of the catheter and provides the mechanism for dilating the vessel. Two (2) lumens extended the entire length of the catheter. The first lumen is designed to accommodate a maximum guidewire diameter of 0.035 inches. The second lumen is used for inflation and deflation of the balloon. The proximal end of the catheter contains a luer adapter with two ports; one port is used for accessing the guidewire lumen while the second port facilitates inflation and deflation of the balloon. A strain relief between the proximal shaft and the luer adapter provides rigidity and transition between the two parts. The delivery catheter is offered in both 80cm and 120cm working lengths.

9. Intended Use:

The Edwards Peripheral Dilation Catheter is intended to:

- dilate stenoses in peripheral arteries,
- treat obstructive lesions of native or synthetic A-V fistulae and/or
- re-expand endoluminal stent graft elements in the aorta and iliac arteries

10. Technological Characteristics:

Comparisons of the subject and predicate devices show that the technical characteristics such as materials, performance properties, biocompatibility, method of sterilization, and packaging are identical or substantially equivalent.

11. Performance Data:

Edwards Lifesciences completed bench testing, such as dimensional testing, balloon minimum burst strength, balloon compliance, balloon inflation/deflation, balloon fatigue and tensile strength testing on the Edwards Peripheral Dilation Catheter. The results indicate that the Edwards Peripheral Dilation Catheter performed in a manner substantially equivalent to the predicate devices cited in item 7 above.

12. Conclusion:

Since the Edwards Peripheral Dilation Catheter has the same intended use, similar performance properties, packaging and sterilization methods, it may be considered substantially equivalent to the predicate devices cited in item 7 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 2 2005

Edwards Lifesciences LLC
c/o Mr. Kevin Drisko
Senior Manager, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K052149
Edwards Peripheral Dilation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 5, 2005
Received: August 11, 2005

Dear Mr. Drisko:

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. Vuchner

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): K052149

Device Name: Edwards Peripheral Dilation Catheter

Indications for Use:

The Edwards Peripheral Dilation Catheter is intended to:

- dilate stenoses in peripheral arteries,
- treat obstructive lesions of native or synthetic A-V fistulae and/or
- re-expand endoluminal stent graft elements in the aorta and iliac arteries

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)

Donna R. Vehmeyer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052149