510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person:	Susan Reynolds, Regulatory Affairs Associate
Date Prepared:	March 15, 2002
Trade Name:	Edwards MC^3 Tricuspid Annulplasty System
Classification Name:	Class II, CFR 870.3800 Annuloplasty Ring, 74 KRH
Predicate Device:	Cosgrove-Edwards™ Annuloplasty System (K923367)
Device Description:	The Edwards MC^3 Tricuspid Annuloplasty System, Model 4900, consists of two primary components; the implantable annuloplasty ring and the template/lanyard assembly (or holder). The implantable annuloplasty ring is constructed of titanium alloy and has a sewing ring margin that consists of a layer of silicone rubber, covered with polyester velour cloth sewn with a single seam.
Indications for Use:	The Edwards MC^3 Tricuspid Annuloplasty System, is intended for use in patients to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.
Comparative Analysis:	It has been demonstrated that the Edwards MC^3 Tricuspid Annuloplasty System is comparable to the predicate device in design, intended use, materials, and principal of operation.
Functional/Safety Testing:	The Edwards MC^3 Tricuspid Annuloplasty System has successfully completed design verification testing.
Conclusion:	The Edwards MC^3 Tricsupid Annuloplasty System 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

Edwards Lifesciences, LLC
c/o Ms. Susan Reynolds
Regulatory Affairs Associate
One Edwards Way
Irvine, CA 92614

APR 17 2002

Re: K020864
Trade/Device Name: Edwards® MC^3 Tricuspid Annuloplasty System, Model 4900, sizes 26, 28, 30, 32, 34, and 36 mm
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: March 15, 2002
Received: March 18, 2002

Dear Ms. Reynolds:

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) 594-4586. 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Edwards MC^3 Tricuspid Annuloplasty System

Indications for Use:

The Edwards® MC^3 Tricuspid Annuloplasty System is intended for use in patients to correct annular dilatation, increase leaftet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020864