AUG 2 6 2003

K032250

510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person:	Susan Reynolds, Regulatory Affairs Associate
Date Prepared:	July 21, 2003
Trade Name:	GeoForm™ Annulplasty Ring
Classification Name:	Class II, CFR 870.3800 Annuloplasty Ring, 74 KRH
Predicate Device(s):	Carpentier-Edwards™ Classic Annuloplasty Ring (K831949) Cosgrove Edwards™ Annuloplasty System (K923367) MC^3 Annuloplasty System (K020864)
Device Description:	The GeoForm Annuloplasty Ring, Model 4200, 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 GeoForm Annuloplasty Ring, Model 4200 is intended for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.
Comparative Analysis:	It has been demonstrated that the GeoForm Annuloplasty Ring is comparable to the predicate device in design, intended use, materials, and principal of operation.
Functional/Safety Testing:	The GeoForm Annuloplasty Ring has successfully completed design verification testing.
Conclusion:	The GeoForm Annuloplasty Ring 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

AUG 2 6 2003

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

Re: K032250
Trade Name: GeoForm™ Annuloplasty Ring, Mitral Model 4200
Regulation Number: 21 CFR 870.3800
Regulation Name: Annulplasty ring.
Regulatory Class: Class II (two)
Product Code: KRH
Dated: July 21, 2003
Received: July 22, 2003

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), 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

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510(k) Number (if known): K032250

Device Name: GeoForm™ Annuloplasty Ring

Indications for Use:

The Edwards® GeoForm™ Annuloplasty Ring is indicated for the correction of mitral valve insufficiency where the lesions are not so severe as to require total valve replacement.

The decision to undertake valvuloplasty can be made only after visual analysis of the lesion present. The most favorable conditions for valvuloplasty using an annuloplasty ring are a combination of a distended natural valve ring associated with supple valve cusps and normal chordae tendineae.

The remodeling valvuloplasty technique with a prosthetic ring may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus.

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient. However, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae tendineae, or chordal hypertrophy.

(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, Respiratory,
and Neurological Devices
510(k) Number K032250

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

(Optional Format 1-2-96)