K023185

DEC 17 2002

Summary of Safety and Effectiveness
per SMDA 1990 and 21 CFR 807.92
AnnuloFlex™ Annuloplasty System

Submitter: Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, Texas 78752
U.S.A.

Contact: Teffany Hankinson
Regulatory Affairs Specialist
Telephone: (512) 435-3202
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Date of Summary: September 19, 2002

Classification Name: Annuloplasty Ring

Common Name: Annuloplasty Ring

Proprietary Name: AnnuloFlex™ Annuloplasty System

Description of Device: The AnnuloFlex™ Annuloplasty System consists of an annuloplasty ring mounted on a holder assembly for implantation in the mitral or tricuspid position. A complete set of instrumentation is available separately to properly size the annulus and implant the annuloplasty ring.

Statement of Intended Use: The Sulzer Carbomedics AnnuloFlex Annuloplasty System is indicated as a reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Technological Comparison: The AnnuloFlex™ Annuloplasty Ring is a flexible annuloplasty ring that can be implanted either as a partial or complete ring, according to the surgeon's preference and/or patient condition. For purposes of this submission, the AnnuloFlex™ Annuloplasty Ring was compared to the following predicate devices:

- Sulzer Carbomedics® AnnuloFlex™ Annuloplasty Ring: flexible complete or partial ring with identical materials, identical manufacturing process, and identical function
- Medtronic Duran Flexible Ring: flexible complete ring with identical function
- Baxter Cosgrove-Edwards Ring: flexible partial ring with identical function

Testing: Results of biocompatibility testing supports that the materials used in the manufacture of the AnnuloFlex™ are non-toxic, non-hemolytic, and non-pyrogenic. Mechanical testing for the AnnuloFlex™ annuloplasty ring includes suture retention testing and demonstrated that the sewing ring fabric is comparable to fabrics used in vascular prostheses. Testing demonstrated that the AnnuloFlex™ Annuloplasty Ring is substantially equivalent to the predicate devices for repair of the mitral or tricuspid valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

Sulzer Carbomedics Inc.
c/o Ms. Teffany Hankinson
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K023185
AnnuloFlex™ Annuloplasty System
Regulation Number: 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: 74 KRH
Dated: September 19, 2002
Received: September 24, 2002

Dear Ms. Hankinson:

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. 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,

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 STATEMENT

510(K) Number: K_____

Device Name: AnnuloFlex™ Annuloplasty System

Indications for Use: The Sulzer Carbomedics AnnuloFlex Annuloplasty System is indicated as a reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023185