

OCT 12 1999

**Sulzer Carbomedics Inc.**1300 East Anderson Lane  
Austin, Texas 78752-1793Phone (512) 435-3200  
FAX (512) 435-3350  
WATS (800) 648-1579 (US and Canada)**510(k) SUMMARY**  
per 21 CFR §807.92

<i>Submitter</i>	<i>Contact</i>
Sulzer Carbomedics Inc. 1300 East Anderson Lane Austin, Texas 78752-1793	Robert M. Wolfarth, CQA Regulatory Affairs Specialist Telephone: (512) 435-3467 Facsimile: (512) 435-3350 E-mail: rwolfarth@carbomedics.com

**Date of Summary:** May 28, 1999  
**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 position. A complete set of instrumentation is available separately to properly size the annulus and implant the annuloplasty ring.

**Statement of Intended Use:** The AnnuloFlex™ System is intended for use in the repair of the human cardiac mitral valve.

**Technological Comparison:** The AnnuloFlex™ Annuloplasty Ring is a flexible annuloplasty ring which 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® AnnuloFlo™ Annuloplasty Ring: rigid ring with nearly 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:** Material biocompatibility testing has been completed that 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 valve.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 12 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Robert M. Wolfarth  
Regualtrov Affairs Specialist  
Sulzer Medica  
Sulzer Carbomedics, Inc.  
1300 East Anderson Lane  
Austin, TX 78752-1793

Re: K992056  
Sulzer Cardomedics® AnnuloFlex™ Annuloplasty System  
Regulatory Class: III (Three)  
Product Code: 74 KRH  
Dated: June 17, 1999  
Received: June 18, 1999

Dear Mr. Wolfarth:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Robert M. Wolfarth

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications For Use

510(k) Number:

K992056

Device Name:

AnnuloFlex System

Indications for Use:

The AnnuloFlex annuloplasty ring is indicated as a reinforcement for repair of the human cardiac mitral valve 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.

*Bette A. Campbell*

(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K992056

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR §801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)