K974648

SULZER *MEDICA*

AUG 4 1998

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

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510(k) SUMMARY
SULZER CARBOMEDICS LOW PROFILE MITRAL ROTATOR

The sterile, single use Sulzer Carbomedics Low Profile Mitral Rotator is intended for use in rotating the CarboMedics® Prosthetic Heart Valve (CPHV™) mitral valve *in situ* when necessary to avoid anatomical obstruction.

The Sulzer Carbomedics Low Profile Mitral Rotator design includes a socket that the bendable Valve Handle is inserted into and locked in place. This allows the surgeon to orient the valve into the position of greatest advantage for each patient. The Low Profile Mitral Rotator will be marked with the corresponding CPHV size on the rotator. The Low Profile Mitral Rotator will be made available in sizes corresponding with previously approved CPHV™ sizes. The Low Profile Valve Rotators are intended for use with the CPHV™ Mitral 700 valve series.

The Sulzer Carbomedics Low Profile Mitral Rotator will be manufactured from polyetherimide previously used with instrumentation approved with the CPHV™. Polyetherimide has a history of use in medical device applications. The Sulzer Carbomedics Low Profile Mitral Rotator has been tested and compared to the predicate device, the Sulzer Carbomedics Extended Mitral Rotator (K951368, June 20, 1995). The results indicate that the Sulzer Carbomedics Low Profile Mitral Rotator is substantially equivalent to the Sulzer Carbomedics Extended Mitral Rotator.

Common name of the Device:	Valve Rotator
Trade name of Proprietary Name:	Sulzer Carbomedics Low Profile Mitral Rotator
Submitter and Contact Person:	Edward E. Newton Sr. Regulatory Affairs Specialist 1300 E. Anderson Lane Austin, Texas 78752 Phone: (512) 435-3407 Fax: (512) 435-3350
Submission Submitted on:	June 29, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 1998

Mr. Edward E. Newton
Sr. Regulatory Affairs Specialist
Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, TX 78752-1793

Re: K974648
Sulzer Carbomedics Low Profile Mitral Rotator
Regulatory Class: unclassified
Product Code: MOP
Dated: June 29, 1998
Received: June 30, 1998

Dear Mr. Newton:

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.

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), promotion, or advertising, 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

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 STATEMENT

510(K) Number (if known): Unknown

Device Name: Sulzer Carbomedics Low Profile Mitral Rotator

Indications for Use: The Sulzer Carbomedics Low Profile Mitral Rotator is intended for use in rotating the CPHV™ mitral valve *in situ* when necessary to avoid anatomical obstruction.

(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 K974648

Prescription Use X OR Over-the-Counter Use ____

(Optional Format 1-2-96)