

K013022

JUN 13 2002

**SULZER MEDICA**

**Sulzer Carbomedics Inc.**

1300 East Anderson Lane  
Austin, Texas 78752-1793

Phone (512) 435-3200  
FAX (512) 435-3350  
WATS (800) 648-1579 (US and Canada)  
www.sulzercarbomedics.com

**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	Lisa Peterson Regulatory Affairs Associate Telephone: (512) 435-3523 Facsimile: (512) 435-3350 E-mail: lpeterson@carbomedics.com

**Date of Summary:** September 5, 2001  
**Common Name:** Vascular Graft  
**Proprietary Name:** Sulzer Vascutek Gelweave Valsalva™ Vascular Prosthesis

**Description of Device:** The Sulzer Vascutek Gelweave Valsalva™ Vascular Graft is a gelatin-sealed, woven polyester graft. The woven polyester material has been impregnated with an absorbable mammalian gelatin which seals the prosthesis in the same manner as the fibrin deposited in traditional preclotting procedures. The gelatin sealant obviates the need for preclotting prior to implantation. This gelatin has been shown to be safe and effective through PMA #P890045 on January 11, 1993.

**Statement of Intended Use:** The Sulzer Vascutek Gelweave Valsalva™ Vascular Graft is indicated for the repair or replacement of damaged and diseased thoracic aorta in cases of aneurysm, dissection or coarctation.

**Technological Comparison:** For purposes of this submission, the Sulzer Vascutek Gelweave Valsalva™ Vascular Prosthesis was compared to the following predicate devices:

- ◆ Sulzer Vascutek Gelweave™ Vascular Prosthesis: K952293 (Straight)

**Testing:** *In vitro* testing which evaluated Base Graft Water Porosity, Blood Porosity, Burst Strength, Tensile Strength, Suture Retention, and Hydrodynamic testing was performed on the Sulzer Vascutek Gelweave Valsalva™. In addition, flow visualization, biocompatibility and animal testing are referenced. The testing demonstrated that the Gelweave Valsalva™ is substantially equivalent to the Gelweave™ graft predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Sulzer Carbomedics, Inc.  
c/o Ms. Lisa Peterson  
Regulatory Affairs Associate  
1300 East Anderson Lane  
Austin, TX 78752-1793

Re: K013022

Trade Name: Sulzer Vascutek® Gelweave Valsalva™ Vascular Prosthesis  
Regulation Number: 21 CFR 870.3460  
Regulation Name: Vascular Graft Prosthesis  
Regulatory Class: Class II (two)  
Product Code: DSY  
Dated: March 13, 2002  
Received: March 15, 2002

Dear Ms. Peterson:

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.

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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) 594-4646. 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,



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

Enclosure

## Indications For Use

*510(K) Number:* Unknown

*Device Name:* Sulzer Vascutek® Gelweave Valsalva™ Vascular Prosthesis

*Indications for Use:* The Sulzer Vascutek® Gelweave Valsalva™ Vascular Prosthesis is indicated for the repair or replacement of damaged and diseased thoracic aorta in cases of aneurysm, dissection or coarctation.

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

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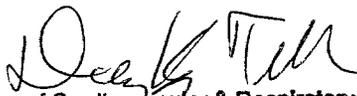
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K013022