DEC - 9 1999

SULZER *MEDICA*

K990503

Sulzer Carbomedics Inc.

1300 East Anderson Lane
Austin, Texas 78752-1793

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510(k) SUMMARY
SULZER VASCUTEK GELSOFT™ VASCULAR PROSTHESIS

The Sulzer Vascutek Gelsoft™ Vascular Prosthesis is a gelatin-sealed, woven polyester graft with a base graft porosity of 2118 ml/cm^2/min. The knitted polyester material has been impregnated with an absorbable mammalian gelatin that 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. The gelatin is of USP standard and is derived from bovine bone sourced exclusively in the United States. The result is a vascular prosthesis that does not require preclotting even when patients have been anticoagulated or when bleeding is a prime concern. The gelatin has been shown to be safe and effective through the approval of PMA P890045 for the Sulzer Vascutek Gelseal™ Vascular Prosthesis on January 11, 1993 and PMA P890045/S1 for the Sulzer Vascutek Gelsoft™ Vascular Prosthesis on July 5, 1995.

Sulzer Vascutek Gelsoft™ Vascular Prosthesis is indicated for abdominal and peripheral vascular repair, i.e. replacement or bypass in aneurysmal and occlusive disease of arteries. Coronary vascular repair and blood access fistula (e.g. hemodialysis) are contraindicated with this device.

The Sulzer Vascutek Gelsoft™ Vascular Prosthesis is manufactured from materials that have an extensive history of use in cardiovascular and other medical applications. The polyester material and gelatin sealant have been thoroughly tested and characterized with regard to biocompatibility and suitability for their intended use. The Sulzer Vascutek Gelsoft™ Vascular Prosthesis is supplied sterile. The method of sterilization used is Ethylene Oxide. A shelf-life of 5 years has been established.

Side-by-side *in vitro* testing which evaluated burst strength, suture retention, tensile strength, and nominal wall thickness was performed using the Sulzer Vascutek Gelsoft™ graft and predicate devices that include the Meadox Hemashield Vantage Graft, Meadox Hemashield Microvel Double Velour Knitted Graft, and Impra ePTFE Graft. This testing demonstrated the acceptable structural and performance characteristics of the Gelsoft™ graft for peripheral vascular repair.

A prospective randomized clinical trial was performed to compare graft patency between the Gelsoft™ and Impra ePTFE grafts for femoropopliteal bypass. The investigators concluded that there was no difference in graft patency between the two grafts.

Sulzer Carbomedics considers the Sulzer Vascutek Gelsoft™ Vascular Prosthesis to be substantially equivalent to the currently marketed predicate devices for peripheral vascular repair.

Common name of the Device:	Vascular Graft
Trade name of Proprietary Name:	Sulzer Vascutek Gelsoft™ Vascular Prosthesis
Submitter and Contact Person:	Edward E. Newton Sr. Regulatory Affairs Specialist 1300 E. Anderson Lane, Austin, TX 78752 Phone: (512) 435-3407 Fax: (512) 435-3350
Submission Submitted on:	February 16, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1999

Mr. Edward E. Newton
Regulatory Affairs Manager
Sulzer Carbomedics Inc.
1300 East Anderson Lane
Austin, Texas 78752

Re: K990503/S2
Sulzer Vasutek Gelsoft Vascular Prosthesis
Regulatory Class: II
Product Code: DSY
Dated: November 4, 1999
Received: November 5, 1999

Dear Mr. Newton:

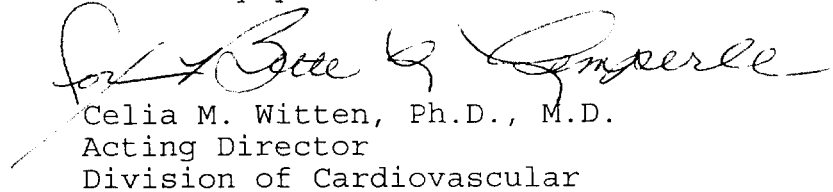
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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), 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Device and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): Unknown

Device Name: Sulzer Vascutek Gelsoft™ Vascular Prosthesis

Indications for Use: Sulzer Vascutek Gelsoft™ Vascular Prosthesis is indicated for abdominal and peripheral vascular repair, i.e. replacement or bypass in aneurysmal and occlusive disease of arteries.

(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 K990503

Prescription Use ✓ OR Over-the-Counter Use ____

(Optional Format 1-2-96)