

APR 14 1998

K972201

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**
SULZER VASCUTEK FLUOROPASSIV™ CARDIOVASCULAR FABRIC

The Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric product line consists of a non-crimped Gelseal™ patch, Gelsoft™ patch, and a Thin Wall Carotid patch. Each patch product line is fluoropolymer coated and gelatin-sealed, knitted polyester, with a base fabric porosity of 1433 ml/cm²/min, 2093 ml/cm²/min, and 3495 ml/cm²/min, respectively, and are available in various square or rectangular sizes. The polyester fabrics have been impregnated with an absorbable mammalian gelatin which seals the prostheses 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 United States Pharmacopeia (USP) standard and is derived from bovine bone. The result is a family of cardiovascular patches that do 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 the Sulzer Vascutek Gelseal™ Vascular Graft, PMA# P890045 on January 11, 1993.

Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric is indicated for vascular patch grafting and for intracardiac patching. The Fluoropassiv™ Thin Wall Carotid Patch is, in addition, indicated for patch closure after endarterectomy, particularly of the carotid arteries. Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric is manufactured from materials that have an extensive history of use in cardiovascular and other medical applications. This polyester material, fluoropolymer, and gelatin sealant have been thoroughly tested and characterized with regard to biocompatibility and suitability for their intended use. Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric is supplied sterile. The method of sterilization used is Ethylene Oxide. A shelf-life of 4 years has been established.

Comprehensive *in vitro* performance testing has been performed on Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric. *In vitro* performance testing performed for the Sulzer Vascutek Fluoropassiv™ Fabric and Sulzer Vascutek Cardiovascular Fabric, which included burst strength, suture retention, tensile strength and water porosity, provides evidence that Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric is substantially equivalent to the predicate fabric. In addition, animal testing demonstrates acceptable *in vivo* performance for the Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric.

Sulzer Carbomedics considers Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric safe, effective and substantially equivalent in intended use and function to the Sulzer Vascutek Cardiovascular Fabric which received marketing clearance on November 21, 1996, under 510(k) K963611.

Common name of the Device: Cardiovascular Patch

Trade name of Proprietary Name: Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric:
Sulzer Vascutek Fluoropassiv™ Gelseal™ Patch
Sulzer Vascutek Fluoropassiv™ Gelsoft™ Patch
Sulzer Vascutek Fluoropassiv™ Thin Wall Carotid Patch

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: June 10, 1997



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K972201
Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric
Regulatory Class: II (Two)
Product Code: 74 DXZ
Dated: April 1, 1998
Received: April 2, 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 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.

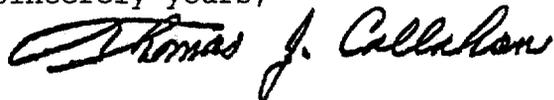
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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" (21 CFR 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/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

510(k) Number (if known): K972201

Device Name: Sulzer Vascutek Fluoropassiv™ Cardiovascular Fabric

Indications For Use: Sulzer Vascutek Fluoropassiv™ Fabric is indicated for vascular patch grafting and for intracardiac patching. The Fluoropassiv™ Thin Wall Carotid Patch is, in addition, indicated for patch closure after endarterectomy, particularly of the carotid 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 K972201

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)