

JAN 28 2000

510(k) SUMMARY

**SULZER VASCUTEK SEALPTFE™
VASCULAR PROSTHESIS**

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)

The Sulzer Vascutek SEALPTFE™ gelatin-sealed expanded polytetrafluoroethylene (PTFE) graft line is substantially equivalent to devices in commercial distribution by Impra, a division of C. R. Bard. All devices referenced under this application are 6mm in diameter or greater and are used to treat diseased or occluded systemic arteries and for A/V access. In addition, the application covers externally supported graft designs.

The device is composed of PTFE, which has been fabricated in tubular form and expanded to impart porosity to the structure. Similar devices have been used clinically since the 1970's with few reported complications or material failures. PTFE typically is used as a synthetic conduit to replace natural vessels or as a shunt for AV/dialysis access. The mechanical properties of Sulzer Vascutek PTFE material such as strength, suture retention, and handling are substantially equivalent to products currently in commercial distribution.

The PTFE material has been impregnated with an absorbable mammalian gelatin that is intended to reduce intra-operative suture hole bleeding. The gelatin is of USP standard and is derived from bovine bone sourced exclusively in the United States. The gelatin used in the impregnation process is a non-antigenic and non-toxic protein. It has been crosslinked to control its dissolution rate. The gelatin hydrolyzes within approximately 14 days. The gelatin is identical to that used with Sulzer Vascutek's gelatin-sealed knitted and woven polyester grafts and knitted cardiovascular fabric.

Sulzer Vascutek SEALPTFE™ grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

In vitro testing conducted on the Sulzer Vascutek SEALPTFE™ graft line shows it to be substantially equivalent to Impra commercial grafts. Results from animal studies demonstrate that the Sulzer Vascutek standard wall grafts to be equivalent to Impra standard wall grafts. Results from biomaterial testing demonstrate that the Sulzer Vascutek SEALPTFE™ grafts are biocompatible and non-toxic.

In summary, all testing demonstrates that the Sulzer Vascutek SEALPTFE™ graft line to be substantially equivalent to the grafts in commercial distribution by Impra, Division of C.R. Bard for the reconstruction and bypass of diseased or occluded systemic blood vessels and construction of subcutaneous a-v conduits for blood access.

Common name of the Device:	Vascular Graft
Trade name of Proprietary Name:	Sulzer Vascutek SEALPTFE™ Vascular Prosthesis
Submitter and Contact Person:	Edward E. Newton Regulatory Affairs Manager 1300 E. Anderson Lane, Austin, TX 78752 Phone: (512) 435-3407 Fax: (512) 435-3350
Submission Submitted on:	October 29, 1999



JAN 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Edward E. Newton
Regulatory Affairs Manager
Sulzer Medica
1300 East Anderson Lane
Austin, TX 78752

Re: K993667
Sulzer Vascutek SEALPTFE™ Vascular Prosthesis
Regulatory Class: II
Product Code: DSY
Dated: October 29, 1999
Received: November 1, 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

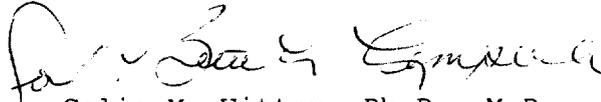
This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

Page 2 - Mr. Edward E. Newton

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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/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 Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): Unknown

Device Name: Sulzer Vascutek SEALPTFE™ Vascular Prosthesis

Indications for Use: Sulzer Vascutek SEALPTFE™ grafts are intended for the creation of subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of occluded or diseased arterial blood vessels. Typical applications for standard wall grafts include systemic vascular repair, primarily for axillo-femoral/bifemoral bypass and femoral-popliteal reconstruction. Typical applications for thin wall grafts include systemic vascular repair, but not for axillo-femoral/bifemoral bypass reconstruction.

(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 K 993667

Prescription Use X

OR

Over-the-Counter Use

(Optional Format 1-2-96)