SEP 8 1999

K991683

Tab 6

Summary of Safety and Effectiveness **Page 1 of 2**

Applicant:

W.L. Gore & Associates, Inc.
3450 West. Kiltie Lane
P.O. Box 500
Flagstaff, AZ 86002-0500

Contact

Timothy J. Rynn

Date Prepared

May 7, 1999

Trade or Proprietary Name

ePTFE Ringed GORE-TEX® Vascular Graft.

Common or Usual Name

Vascular Graft Prosthesis

Classification Name

Vascular Graft Prosthesis less than 6 mm diameter.

Device Predicates

GORE-TEX Vascular Grafts; IMPRA Flex PTFE Vascular Grafts; Atrium Hybrid PTFE Vascular Grafts.

Device Description

The ePTFE Ringed GPRE-TEX® Vascular Graft is an expanded polytetrafluoroethylene (ePTFE) vascular graft base tube with ePTFE reinforcing film and optional manufacturing modifications. The proposed modifications consist of replacing external, semi-rigid reinforcing rings of fluorinated ethylene propylene (FEP) with rings created within the graft wall of the ePTFE. These ring structures alternate with a typical graft structure the entire length of the graft. Additionally, small gold dots may be placed at intervals anywhere along the graft, in conjunction with, or as an alternative to the blue orientation markers. The proposed modifications do not present new issues of safety and effectiveness compared to predicate vascular grafts.

Statement of Intended Use

The ePTFE Ringed GORE-TEX Vascular Graft is intended for use as a vascular prosthesis for replacement or bypass of diseased vessels in patients suffering occlusive or aneursymal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

Substantial Equivalence

The applicant device is substantially equivalent in materials to currently marketed ePTFE vascular grafts. Mechanical testing data demonstrate the applicant device has mechanical characteristics substantially equivalent to the predicate devices. *In vivo* testing demonstrates that applicant device performance is substantially equivalent to the predicate devices.

The applicant device is composed of the same ePTFE biomaterial as other GORE-TEX® Vascular Grafts

No new types of safety and effectiveness issues are raised by the modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1999

Mr. Timothy J. Rynn
Regulatory Associate
W.L. Gore & Associates, Inc.
3450 West Kiltie Lane
P.O. Box 500
Flagstaff, AZ 86002-0500

Re: K991683
ePTFE Ringed GORE-TEX® Vascular Graft Class III
Regulatory Class: III (Three)
Product Code: DYF
Dated: May 14, 1999
Received: May 17, 1999

Dear Mr. Rynn:

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,

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

Tab 7

Indications For Use

Page _____ of ____

510(k) Number (if known) _____

Device Name: ePTFE Ringed GORE-TEX® Vascular Graft

INDICATIONS FOR USE:

The ePTFE Ringed GORE-TEX® Vascular Graft is intended for use as a vascular prosthesis for replacement or bypass of diseased vessels in patients suffering occlusive or aneursymal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991683

®GORE-TEX is a registered trademark of W.L. Gore & Associates, Inc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(per 21 CFR 801.109)

(Optional Format 1-2-96)