510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

NOV - 9 2006

Proprietary Name:	GORE PROPATEN Vascular Graft
Common Name:	Vascular Graft
Classification Name:	Prosthesis, Vascular Graft of 6 mm and greater diameter (per 21 CFR 870.3460)
Device Classification:	Class II
Product Classification and Code:	DSY
Classification Panel:	Cardiovascular Devices

Establishment Registration Number: 2017233

Contact Person: Michael Ivey
Regulatory Affairs
Medical Products Division
W. L. Gore & Associates, Inc.
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Performance Standards

The GORE PROPATEN VASCULAR GRAFT has been tested, or rationale has been provided, to meet all applicable sections of *Cardiovascular Implants-Vascular Prostheses AAMI / ANSI / ISO 7198:1998/2001(R) 2004.*

Device Description

The GORE PROPATEN Vascular Graft is constructed from the same materials used in the predicate devices: the GORE-TEX Vascular Graft, the GORE-TEX Stretch Vascular Graft, and the FEP Ringed GORE-TEX Stretch Vascular Graft with Removable Rings, which have a successful history of clinical use and were cleared for use in the United States through the Premarket notifications K830806, K903931 and K933943.

The GORE PROPATEN Vascular Graft is a biocompatible device comprised of expanded polytetrafluoroethylene (ePTFE) with covalently bound, luminal, bioactive heparin. The heparin used in creating this device has been derivatized by a proprietary process established by Carmeda AB, Stockholm, Sweden. The heparinization process is based upon the Carmeda Bioactive Surface (CBAS™) technology. Heparin activity is retained in a binding process that does not interfere with the heparin active site.

Indications for Use

GORE PROPATEN VASCULAR GRAFT is intended for use as a vascular prosthesis for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

Substantially Equivalent Devices

W.L. Gore and Associates cites the following devices as substantially equivalent predicate devices listed below:

- GORE-TEX® Vascular Graft **(K830806)**
- GORE-TEX® Stretch Vascular Graft **(K903931)**
- FEP Ringed GORE-TEX® Stretch Vascular Graft with Removable Rings **(K933943)**

Conclusion (Statement of Equivalence)

The data and information presented show numerous similarities between the predicate devices and the applicant device, which support a determination of substantial equivalence, and therefore market clearance, of the GORE PROPATEN Vascular Graft through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2006

W. L. Gore & Associates, Inc.
c/o Mr. Michael Ivey
Regulatory Affairs
3450 West Kiltie Lane
P.O. Box 2400
Flagstaff, AZ 86003-2400

Re: K062161
GORE PROPATEN™ Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II (Two)
Product Code: DSY
Dated: October 5, 2006
Received: October 6, 2006

Dear Mr. Ivey:

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.

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062161

INDICATION FOR USE

510(k) Number (if known): TBD

Device Name: GORE PROPATEN VASCULAR GRAFT

Intended Use / Indication For Use: GORE PROPATEN VASCULAR GRAFT is intended for use as a vascular prosthesis for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bolmsen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062161