K093934

MAR 17 2010

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE HYBRID Vascular Graft
Common Name:	HYBRID Vascular Graft
Classification Name:	Vascular Graft Prosthesis (per 21 CFR 870.3450)
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.
3250 West Kiltie Lane
Flagstaff, AZ 86001-0500

Telephone: (928) 864-3790
Facsimile: (928) 779-4219
E-mail: *mivey@wlgore.com*

Performance Standards

Performance standards do not currently exist for these devices. None are established under Section 514.

Device Description

The GORE HYBRID Vascular Graft is an ePTFE vascular prosthesis that has a section reinforced with nitinol. The nitinol reinforced section (NRS) is partially constrained to allow for easy insertion and deployment into a vessel to form an end-to-end anastomosis. The constraint is made up of an ePTFE fiber which is knitted into a tubular shape. The GORE HYBRID Vascular Graft with a continuous lumen and has immobilized heparin bonded to the luminal surface.

Indications for Use

The GORE HYBRID Vascular Graft is indicated 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 & Associates cites the following devices as substantially equivalent predicate devices listed below:

- GORE PROPATEN® Vascular Graft **(K062161)** Cleared November 9, 2006
- GORE VIABAHN® Endoprosthesis **(K013648)** Cleared January 8, 2002
- ATRIUM Graduated Wall Flixene Graft **(K071923)** Cleared August 14, 2007
- ATRIUM Advanta T-Graft **(K051332)** Cleared September 29, 2005

Brief Comparison Summary

To demonstrate substantial equivalence of the applicant GORE HYBRID Vascular Graft to the predicate devices, the technological characteristics and performance criterion were evaluated using *in vitro* and *in vivo* testing performed in accordance with ISO 7198:1998 "Cardiovascular Implants - Tubular Vascular Prostheses" and ISO 25539-1: 2003 "Cardiovascular Implants – Endovascular Devices" as outlined below:

***In Vitro* Testing**

Using FDA guidance documents on non-clinical testing of medical devices the following in vitro tests were performed:

- Wall thickness
- Internal and External Diameter
- Suture Retention (transverse and longitudinal)
- Kink Radius (Pressurized and Non-Pressurized)
- Repeated Punctured Burst
- Burst Testing
- Water Entry Pressure (WEP)
- Tensile Strength
- Constrained Profile
- Deployment Accuracy
- Deployment Force
- Deployment Reliability
- Pre and Post Deployment Dimensional Testing
- Nitinol Reinforced Section (NRS) Flexibility
- Radial Compression Resistance
- Integral Water Permeability
- Fibril Length
- Pressurized Internal Diameter
- Tensile Strength
- Corrosion Testing
- Simulated Device Use

The results from these tests demonstrate that the technological characteristics and performance criteria of the GORE HYBRID Vascular Graft are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

***In Vivo* Testing**

To assess the performance of the GORE HYBRID Vascular Graft, as well as evaluate the biocompatibility of the graft in a vascular application, an *in vivo* study was conducted in a canine model to evaluate 3 device attributes:

- **Device Deployment:** the device can be accurately and easily deployed at the desired location by the surgeon.
- **Device Sealing:** the device achieves hemostasis successfully post deployment and allows for closure of the incision site by the surgeon.
- **Device Patency:** The implanted device remains patient and in position throughout the in-life period in the canine model. This was assessed visually and via palpation by the surgeon.

The results of this study show that the GORE HYBRID Vascular Graft can be successfully delivered, deployed, remain patent, and maintain position at the intended target location. The device is well tolerated with no deleterious tissue response observed within a normal arteriovenous canine test system.

Conclusion (Statement of Equivalence)

W.L. Gore & Associates Inc. believes that the data and information presented in this application, including *in vitro* testing, *in vivo* animal data, and numerous device similarities support a determination of substantial equivalence, and therefore market clearance of the GORE HYBRID Vascular Graft through this 510(k) Premarket Notification

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

W.L. Gore & Associates, Inc.
c/o Mr. Michael Ivey
Regulatory Affairs
Medical Products Division
3250 Kiltie Lane
P. O. Box 2400
Flagstaff, AZ 86001

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Re: K093934
GORE HYBRID Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: December 18, 2009
Received: December 22, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

INDICATION FOR USE

510(k) Number (if known):	~~TBD~~ K093934
Device Name:	GORE HYBRID Vascular Graft
Intended Use / Indication For Use:	The GORE HYBRID Vascular Graft is indicated 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use (Optional Format 1-2-96)

Susan R Mitchell
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093934