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K063435

510(k) Summary of Substantial Equivalence (21 CFR 807.92)

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Applicant:

W.L. Gore and Associates Inc.
3250 W. Kiltie Lane
Flagstaff, AZ 86001

Contact person:

Michael E. Ivey

Date Prepared:

November 10, 2006

Trade or Proprietary Name:

GORE DUALMESH® PLUS BIOMATERIAL
GORE MYCROMESH® PLUS BIOMATERIAL

Common or Usual Name:

Polymeric Surgical Mesh

Classification

21 CFR 878.3300, FTL: General and Plastic Surgery Devices

Device Predicate:

GORE DUALMESH® PLUS BIOMATERIAL (K946106)

Device Description:

The GORE DUALMESH® PLUS and GORE MYCROMESH® PLUS Biomaterials are patch materials composed solely of expanded polytetrafluoroethylene (ePTFE) loaded with two antimicrobial preservative agents, chlorhexidine diacetate and silver carbonate (referred to as PLUS). The device incorporates a microporous node and fibril structure with regularly spaced macropores. This structure ensures early fixation to host tissue with minimal foreign body response and extensive vascularization. The PLUS acts as a preservative and prevents bacterial colonization of the device during the short-term postoperative period. The GORE DUALMESH PLUS Biomaterial is intended for reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The device is available in 1 mm, 1.5 mm, and 2 mm thicknesses.

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Statement of Intended Use:

The GORE DUALMESH® PLUS and GORE MYCROMESH® PLUS Biomaterials are indicated for use in the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects.

Substantial Equivalence:

Tests, assessments, and comparisons contained within this submission demonstrate that the GORE DUALMESH® PLUS and GORE MYCROMESH® PLUS Biomaterials are substantially equivalent to the predicate device in terms of composition, design, intended use, mode of operation and performance attributes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2006

W.L. Gore & Associates, Inc.
% Mr. Michael Ivey
Regulatory Affairs
Medical Products Division
3450 West Kiltie Lane
P.O. Box 2400
Flagstaff, Arizona 86003-2400

Re: K063435
Trade/Device Name: GORE DUALMESH® PLUS Biomaterial
GORE MYCROMESH® PLUS Biomaterial
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: November 10, 2006
Received: November 13, 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) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063435

XIV. Indications for Use Statement

510(k) Number (if known):	TBD
Device Name:	GORE DUALMESH® PLUS Biomaterial GORE MYCROMESH® PLUS Biomaterial
Indications for Use:	**Reconstruction of Hernias and Soft Tissue Deficiencies and for the Temporary Bridging of Fascial Defects**

Prescription Use ✓ (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063435