AUG 15 2003

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510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE-TEX DualMesh EMERGE PLUS Biomaterial
Common Name:	Surgical Mesh
Classification Name:	Surgical Mesh
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery Devices
Establishment Registration Number:	2025240
Contact Person:	Brandon Hansen Regulatory Affairs Medical Products Division W.L. Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86001 Telephone: (928) 864-3784 Facsimile: (928) 864-4144 E-mail: *bhansen@wlgore.com*

Performance Standards

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

Device Description

The GORE-TEX DualMesh EMERGE PLUS Biomaterial consists of an ePTFE mesh coated with silver carbonate and chlorhexidine diacetate and a silicone component attached to the closed microstructure side of the ePTFE component with a silicone adhesive. The silicone component is designed to provide a stiffening

effect to the ePTFE component thereby making the ePTFE material more rigid and improving its handling characteristics. The silicone component provides both stiffness and easier unrolling in order to aid in placement and fixation of the ePTFE component.

Indication for Use

GORE-TEX DualMesh EMERGE PLUS Biomaterial is indicated for the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of facial defects.

Substantially Equivalent Devices

In W.L. Gore & Associates' opinion, the GORE-TEX DualMesh EMERGE PLUS Biomaterial is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- GORE-TEX DualMesh EMERGE and EMERGE PLUS Biomaterial (W.L. Gore & Associates, Inc., Flagstaff, AZ) – K022782
- GORE-TEX DualMesh PLUS Biomaterial (W.L. Gore & Associates, Inc., Flagstaff, AZ) – K000185, K981051, K965038, K946106

Labeling, packaging and sterilization of the GORE-TEX DualMesh EMERGE PLUS Biomaterial has not changed from that of the predicate devices listed above.

Summary of Studies

W.L. Gore & Associates, Inc. performed device integrity testing to support that the GORE-TEX DualMesh EMERGE PLUS Biomaterial is equivalent to the predicate devices. All device integrity test results for the GORE-TEX DualMesh EMERGE PLUS Biomaterial met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the W. L. Gore & Associates, Inc. GORE-TEX DualMesh EMERGE PLUS Biomaterial through this Special 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2003

Mr. Brandon Hansen
Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 West Kiltie Lane
Flagstaff, Arizona 86001

Re: K032168
Trade/Device Name: GORE-TEX DualMesh EMERGE PLUS Biomaterial
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: July 15, 2003
Received: July 17, 2003

Dear Mr. Hansen:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K032168

Device Name: GORE-TEX DualMesh EMERGE PLUS Biomaterial

Intended Use / Indication For Use: GORE-TEX DualMesh EMERGE PLUS Biomaterial is indicated for the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of facial defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

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

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

510(k) Number K032168