K022782

SEP 1 0 2002

Attachment IV

Special 510(k) Premarket Notification

DualMesh® EMERGE Biomaterial and DualMesh® EMERGE PLUS Biomaterial

Premarket Notification 510(k) Summary

A. Submitter

W.L. Gore and Associates, Inc.
3750 W. Kiltie Lane
P.O. Box 900
Flagstaff, AZ 86002-0900

Contact: R. Larry Pratt

Date Submitted: August 21, 2002

B. Applicant Device

Trade Name: DualMesh® EMERGE Biomaterial and DualMesh® EMERGE PLUS Biomaterial

Classification Name: Surgical Mesh

C. Applicant Device Description

Biocompatible, expanded polytetrafluoroethylene (ePTFE) with a removable, tinted silicone component (DualMesh® EMERGE Biomaterial). Biocompatible, ePTFE loaded with antimicrobial preservative agents chlorhexidine diacetate and silver carbonate with a removable, tinted silicone component (DualMesh® EMERGE PLUS Biomaterial). Both devices have one open microstructure surface and one closed microstructure surface. The open microstructure surface is textured with a "ridges and valleys" pattern to aid in surface identification and proper surface orientation.

D. Applicant Device Indications For Use

DualMesh® EMERGE Biomaterial and DualMesh® EMERGE PLUS Biomaterial are indicated for use in the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The antimicrobial preservative agents act as preservatives, thereby inhibiting bacterial colonization of the device for up to ten days post-implantation. The removable, tinted silicone component facilitates introduction and fixation of the biomaterial. Following fixation of the biomaterial, the silicone component is easily removed.

E. Predicate Device

The previously cleared GORE-TEX® DualMesh® Biomaterial and GORE-TEX® DualMesh® PLUS Biomaterial are cited as the predicate devices.

F. Technological Characteristics

This Premarket Notification submission is for a modification to an existing, currently marketed device. The modification is to attach a silicone component to the closed microstructure surface of the ePTFE biomaterial. The silicone component is removed following fixation of the ePTFE component and is not implanted.

These changes do not change the device's intended use or indications. Similarly, the biocompatibility, packaging and sterilization process for the applicant devices have not changed from those for the predicate device.

Bench test data reveal the applicant devices have mechanical strength and material characterization values that are substantially equivalent to the predicate devices.

In-vitro antimicrobial activity test data demonstrate that the antimicrobial version of the applicant device functions both safely and effectively to inhibit bacterial colonization of the device for up to ten days post-implantation.

In-vivo animal test data document that the tissue response for the applicant devices is equivalent to histological controls for the predicate devices.

Design control and verification testing have been performed for this device modification.

G. Safety and Effectiveness Conclusions

This Premarket Notification submission concerns a modification to existing, currently marketed devices. The modification is to attach a silicone component to the closed microstructure surface of the ePTFE biomaterial. The silicone component is removed following fixation of the ePTFE component and is not implanted. The implanted portion of the applicant devices is identical to the implanted portion of the predicate devices.

Bench testing, *in-vivo* animal testing and *in-vitro* antimicrobial testing demonstrate the applicant devices perform equivalent to the predicate devices.

The modification described in this Premarket Notification does not raise questions of safety or effectiveness that have not been previously addressed. Both the applicant devices and the predicate devices perform their equivalent clinical functions by incorporating biocompatible materials to permanently or transiently bridge or support a tissue defect. The antimicrobial agents loaded on both the applicant DualMesh® EMERGE PLUS device and the predicate GORE-TEX® DualMesh® PLUS device perform an equivalent preservative function by inhibiting bacterial colonization for up to ten days post-implantation.

The applicant devices are substantially equivalent to the previously cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2002

W. L. Gore and Associates, Inc.
R. Larry Pratt
Regulatory Affairs
3750 West Kiltie Lane
P.O. Box 900
Flagstaff, Arizona 86002-0900

Re: K022782
Trade/Device Name: DualMesh® EMERGE and EMERGE PLUS Biomaterial
Regulation Number: 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: Class II
Product Code: FTL
Dated: August 21, 2002
Received: August 22, 2002

Dear Mr. Pratt:

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.

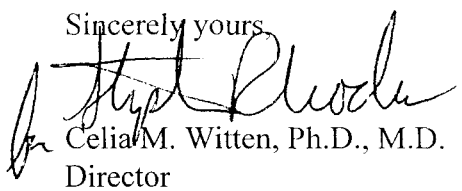
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K022782

Device Name: DualMesh® EMERGE Biomaterial
DualMesh® EMERGE PLUS Biomaterial

Indications For Use:

For the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K022782

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)