K981051

APR 15 1998

Premarket Notification Summary

1. **Submitter:** W. L. Gore & Associates, Inc.
3750 West Kiltie Lane
Flagstaff, Arizona 86002-0900
Phone: (520) 779-2771
FAX: (520) 779-1456

Contact: John W. Nicholson, Regulatory Affairs
Preparation Date: March 30, 1998

2. **Applicant**

Device: Trade Name: GORE-TEX® Soft Tissue Patch PLUS Biomaterial
GORE-TEX® MycroMesh PLUS Biomaterial
GORE-TEX® DualMesh PLUS Biomaterial
GORE-TEX® DualMesh PLUS Biomaterial with Holes

Common Name: Surgical Mesh

3. **Substantially Equivalent Devices:**

These four devices were cleared for an indication revision (the addition of the clause, "and for the temporary bridging of fascial defects" to the existing cleared indication) under K 965038, and so these products will serve as their own predicates.

4. **Device Description:**

These devices are composed of expanded polytetrafluoroethylene (ePTFE) and antimicrobial agents. GORE-TEX ePTFE Medical Products have been available for more than two decades and the safety and efficacy of these devices have been confirmed by well over 5,000,000 implants. The applicant devices are intended for long-term implantation as reinforcing surgical meshes. They incorporate the antimicrobial agents silver carbonate and

chlorhexidine diacetate to inhibit bacterial colonization of the device for up to ten days post-implantation. The only change which will result to the applicant devices as a result of the clearance of K 981051 is the addition of the contraindication, **" Not for pre-term and neonatal populations".**

5. Intended Use:

The applicant devices will have the same intended uses as those of the cited predicates : For the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects.

6. Technological Characteristics:

No new technological characteristics result from the addition of the presented contraindication. The applicant devices' design, performance and material characteristics are not being changed in any way and only the labeling is revised as a result of this submission's clearance. Therefore, no technological characteristic revisions have occurred when comparing the applicant devices with their cited, substantially equivalent predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 1998

Mr. John Nicholson
Regulatory Affairs Associate
W.L. Gore & Associates, Incorporated
Medical Products Division
P.O. Box 900
3750 West Kiltie Lane
Flagstaff, Arizona 86002-0900

Re: K981051
Trade Name: GORE-TEX® Soft Tissue Patch PLUS;
GORE-TEX® DualMesh PLUS Biomaterrial;
GORE-TEX® MycroMesh PLUS Biomaterial; and
GORE-TEX® DualMesh PLUS Biomaterial with
Holes
Regulatory Class: II
Product Code: FTL
Dated: March 17, 1998
Received: March 18, 1998

Dear Mr. Nicholson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Mark N Melkerson

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

Enclosure

510(k) Number (if known): K 981051

Device Name: Gore-Tex Soft Tissue Patch Plus, Gore-Tex MycroMesh Biomaterial, ~~Gore-Tex DualMesh Biomaterial~~, Gore-Tex-MycroMesh Plus Biomaterial, Gore-Tex DualMesh Plus Biomaterial with holes

Indications For Use:

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

Mark N Milleson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981051

for cmw

(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)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)