K 013346

DEC 1 9 2001

TAB J

510(K) Summary of Safety and Effectiveness

1. **Applicant Name, Address:** W.L. Gore & Associates, Inc.
3450 W. Kiltie Lane
P.O. Box 900
Flagstaff, AZ 86002-0900

Contact Person: Jacqueline Kalbach
(928)864-3731

Date of Summary: October 5, 2001

2. **Classification Name:** Resorbable Barrier Membrane

Common or Usual Name: Regenerative Material

Proprietary Name: To be determined

3. **Device Description:**

GORE DRAPEABLE ST and LT Regenerative Membranes are composed of a porous structure of synthetic resorbable glycolide and trimethylene carbonate copolymer fiber. The fiber web is designed to allow attachment to surrounding tissues, stabilize the wound and blood clot, inhibit epithelial down-growth, and isolate the healing defect during the initial phases of wound healing. GORE DRAPEABLE ST and LT Regenerative Membranes have been designed to act in accordance with the accepted principles of wound healing and regenerative therapy. Specifically, the membranes are designed to be biocompatible, separate tissue (cell occlusive), clinically manageable, and allow for tissue integration. The fifth requirement for regenerative therapy is spacemaking, and bone grafting or bone filling materials may be used in conjunction with the membranes to assist in providing the space necessary for regenerative healing. GORE DRAPEABLE ST and LT Regenerative Membranes are surgically placed beneath the mucoperiosteum to aid in the regenerative healing of bone and periodontal ligament defects of the oral cavity or, when placed over bone graft material, to prevent graft material migration.

4. **Intended Use:**

GORE DRAPEABLE ST and LT Regenerative Membranes are bioabsorbable, implantable materials intended to aid in the healing of periodontal and bone defects. They may also be used as a membrane for bone graft containment. When used over a bone graft, GORE DRAPEABLE ST and LT Regenerative Membranes provide a stable barrier to prevent migration of bone graft material and provides a favorable environment for bone regeneration. When used in the treatment of non-spacemaking defects, GORE DRAPEABLE ST and LT Regenerative Membranes should be used in combination with spacemaking bone graft materials (e.g., autogenous bone, bone substitutes).

5. **Technological Characteristics:**

GORE DRAPEABLE ST and LT Regenerative Membranes have been designed to act in accordance with the accepted principles of wound healing and regenerative therapy. Specifically, the membranes are designed to be biocompatible, separate tissue (cell occlusive), clinically manageable, and allow for tissue integration. The fifth requirement for regenerative therapy is spacemaking, and bone grafting or bone filling materials may be used to provide the space necessary for regeneration.

6. **Assessment of Performance Data:**

Preclinical studies conducted in critical size defects of the rat mandible indicate that GORE DRAPEABLE ST and LT Regenerative Membranes provide protection of the regenerative environment and tissue tolerance suitable for regeneration of bone. The functional integrity and time to absorption of this material are consistent with the clinical goals of regenerative therapy.

7. **Conclusion:**

The modified GORE DRAPEABLE ST and LT Regenerative Membranes have an indication statement that is similar to the current GORE RESOLUT XT and GORE OSSEOQUEST Regenerative Membranes. Their intended use is the same: the modified GORE DRAPEABLE ST and LT Regenerative Membranes act as a barrier intended to allow controlled tissue regeneration and thus allow repair of periodontal and bone defects in the oral cavity. They may also be used as membranes for bone graft containment, and bone grafting or bone filling materials may be used in conjunction with the membranes to assist in providing the space necessary for regenerative healing. Thus, the modified GORE DRAPEABLE ST and LT Regenerative Membranes are substantially equivalent to the current GORE RESOLUT XT and GORE OSSEOQUEST Regenerative Membranes. The indication statement has been modified, and the added

wording is consistent with that of other legally marketed resorbable regenerative membranes that also recommend the use of bone filling materials when non-spacemaking defects are treated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Ms. Jacqueline Kalbach
Regulatory Affairs Associate
W. L. Gore & Associates
Medical Products Division
3450 Kiltie Lane
P.O. Box 500
Flaggstaff, Arizona 86002-0500

Re: K013346
Trade/Device Name: Gore Drapeable St/Lt Regenerative Membrane
Regulation Number: None
Regulation Name: Regenerative Material
Regulatory Class: Unclassified
Product Code: LYC
Dated: October 5, 2001
Received: October 9, 2001

Dear Ms. Kalbach:

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) 594-4613. 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" (21CFR 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013346

510(k) Number (if known) K013346

Device Name: GORE DRAPEABLE ST and LT Regenerative Membranes

INDICATIONS FOR USE:

GORE DRAPEABLE ST and LT Regenerative Membranes are bioabsorbable, implantable materials intended to aid in the healing of periodontal and bone defects. They may also be used as a membrane for bone graft containment. When used over a bone graft, GORE DRAPEABLE ST and LT Regenerative Membranes provide a stable barrier to prevent migration of bone graft material and provides a favorable environment for bone regeneration. When used in the treatment of non-spacemaking defects, GORE DRAPEABLE ST and LT Regenerative Membranes may be used in combination with spacemaking bone graft materials (e.g., autogenous bone, bone substitutes).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Ryan

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013346