DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 10 2007

Ms. Jacqueline Kalbach
Regulatory Affairs Associate
W.L. Gore & Associates, Incorporated
1500 North Fourth Street
Flagstaff, Arizona 86001

Re: K960292
Trade Name: Gore-Tex Regenerative Material Titanium Reinforced Configurations
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPK
Dated: January 19, 1996
Received: January 22, 1996

Dear Ms. Kalbach:

This letter corrects our substantially equivalent letter of April 15, 1996.

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 (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 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 continue 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/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Protecting and Promoting Public Health

K960892

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K960892

APR 15 1996

1. **Applicant Name, Address**: W.L. Gore & Associates, Inc.
1500 North Fourth Street
P.O. Box 2500
Flagstaff AZ 86003-2500

Contact Person, Telephone: Jacqueline Kalbach
(520)527-2295

Date of Summary: January 19, 1996

2. **Classification Name**: Nonresorbable Barrier Membrane
Common or Usual Name: Regenerative Material
Proprietary Name: GORE-TEX Regenerative Material -- Titanium Reinforced Configurations

3. **Predicate Device**: GORE-TEX Periodontal Material -- Titanium Reinforced Configurations

4. **Device Description**:

The Titanium Reinforced Configurations of GORE-TEX Regenerative Material are designed to act in accordance with the accepted principles of wound healing and guided tissue regeneration (GTR). Specifically, the device is designed to be biocompatible, cell occlusive, spacemaking, and clinically manageable, and allow for tissue integration. The materials used in the manufacture of the Titanium Reinforced Configurations do not alter the biology of GTR therapy or the application for which the product is presently used.

GORE-TEX Regenerative Material is surgically placed beneath the muco-periosteum to aid in the regenerative healing of (1) bone or (2) bone/periodontal

ligament defects of the oral cavity. The material is designed to be a passive barrier which excludes epithelial and gingival connective tissue from the defect site so that only the desirable cells repopulate the space, allowing regeneration to occur.

The material is designed to be stiff enough to create and maintain a protected defect space into which new hard and soft tissues can form, but supple enough to drape smoothly over the defect margin. It is non-absorbable, thereby allowing for predictable isolation of the defect site.

5. **Intended Use**:

GORE-TEX Regenerative Material is intended to provide a mechanism for the ingrowth of new hard and soft tissues into bony defects surrounding teeth and to augment ingrowth of hard and soft tissues on alveolar ridges. GORE-TEX Regenerative Material is a passive, non-load bearing material. It is NOT intended for use in load bearing, articulating situations such as temporal mandibular joint reconstruction.

6. **Technological Characteristics**:

The modified Titanium Reinforced Configurations of GORE-TEX Regenerative Material have been designed according to the same five design criteria as the predicate device, GORE-TEX Periodontal Material -- Titanium Reinforced Configurations. The additional raw material has reduced the complexity of the manufacturing process.

7. **Assessment of Performance Data**:

Lamination is an important characteristic and testing of the lamination bond strength was performed. The bond values for the modified Titanium Reinforced Configurations are comparable to or better than those of the current Titanium Reinforced Configurations.

8. **Conclusion**:

The modified Titanium Reinforced Configurations of GORE-TEX Regenerative Material are substantially equivalent to the current Titanium Reinforced Configurations of GORE-TEX Regenerative Material in design, manufacturing process, materials, and intended use.