K973594

DEC 17 1997

TAB I

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Applicant Name, Address:** W.L. Gore & Associates, Inc.
3750 W. Kiltie Lane
P.O. Box 900
Flagstaff, AZ 860023-0900

Contact Person, Telephone: John W. Nicholson
(520)779-2771

Date of Summary: August 15, 1997

2. **Classification Name:** Resorbable Barrier Membrane
Common or Usual Name: Regenerative Material
Proprietary Name: GORE RESOLUT™ XT Regenerative Material

4. **Device Description:**

GORE RESOLUT™ XT Regenerative Material is composed of a porous structure of synthetic bioabsorbable glycolide and trimethylene carbonate copolymer fiber and an occlusive membrane of synthetic bioabsorbable glycolide and lactide copolymer. The porous structure is designed to attach to surrounding soft tissue and inhibit epithelial migration, while the occlusive membrane isolates the periodontal defect from gingival connective tissue during wound healing. GORE RESOLUT™ XT Regenerative Material has been 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. GORE RESOLUT™ XT Regenerative Material is surgically placed beneath the the mucoperiosteum to aid in the regenerative healing of bone/periodontal ligament defects of the oral cavity or, when placed over bone graft material, to prevent graft material migration.

5. **Intended Use:**

GORE RESOLUT™ XT Regenerative Material is a bioabsorbable, implantable material intended to aid in the healing of periodontal defects. It may also be used as a membrane for bone graft containment. When used over a bone graft, GORE RESOLUT™ XT Regenerative Material provides a stable barrier to graft material migration and provides a favorable environment for bone regeneration.

6. **Technological Characteristics:**

GORE RESOLUT™ XT Regenerative Material has been 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, space-making, and clinically manageable, and allow for tissue integration.

7. **Assessment of Performance Data:**

Preclinical studies conducted in critical size defects of the rat mandible indicate (1) that GORE RESOLUT™ XT Regenerative Material provided space maintenance and a tissue tolerance suitable for regeneration of intramembranous bone. The functional integrity and time to absorption of this material are consistent with the clinical goals of GTR.

8. **Conclusion:**

The modified GORE RESOLUT™ XT Regenerative Material has the same indication statement as the current GORE RESOLUT™ Regenerative Material. Their intended use is the same: the modified GORE RESOLUT™ XT Regenerative Material acts as a barrier intended to allow controlled tissue regeneration and thus allow repair of bone/periodontal ligament defects in the oral cavity. It may also be used as a membrane for bone graft containment. Trimethylene carbonate has been added to the manufacture of the modified GORE RESOLUT™ XT Regenerative Material, and trimethylene carbonate has a long history of safe and effective use in bioabsorbable, implantable medical devices. Thus, the modified GORE RESOLUT™ XT Regenerative Material is substantially equivalent to the current GORE RESOLUT™ Regenerative Material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

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

Re: K973594
Trade Name: Gore Resolut XT Regenerative Material
Regulatory Class: Unclassified
Product Code: LYC
Dated: September 19, 1997
Received: September 22, 1997

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) 594-4618. 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,

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

Enclosure

510(k) Number (if known): K973594

Device Name: GORE RESOLUT XT Regenerative Material

Indications For Use:

GORE RESOLUT XT Regenerative Material is a bioabsorbable, implantable material intended to aid in the healing of periodontal defects. It may also be used as a membrane for bone graft containment. When used over a bone graft, GORE RESOLUT XT Regenerative Material provides a stable barrier to graft material migration and provides a favorable environment for bone regeneration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973594

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)