

K983525

DEC 10 1998

SECTION 2

Premarket Notification Summary

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

Contact: John W. Nicholson, Regulatory Affairs
Preparation Date: October 7, 1998

2. Applicant

Device: Trade Name: GORE ReVox Thyroplasty Implant
Common Name: Thyroplasty Implant
Classification Name: Ear, Nose and Throat Synthetic Polymer
Material

3. Substantially Equivalent Devices:

GORE cites the following as predicate devices to which substantial equivalence will be established:

- Boston Medical Products - Montgomery® Thyroplasty Implant
- Smith & Nephew - VoCoM® (Vocal Cord Medialization) System
- W.L. Gore & Associates, Inc. - GORE Subcutaneous Augmentation Material (S.A.M.)

4. Device Description:

The GORE ReVox Thyroplasty Implant is composed solely of expanded polytetrafluoroethylene (ePTFE), which is extremely inert and has excellent chemical and thermal stability. The carbon-fluorine bond is one of the strongest bonds known among organic compounds. The highly electronegative fluorine atoms form a protective sheath enveloping the chain of carbon atoms. This sheath

effectively shields the carbon chain from attack by nearly all chemicals and is responsible for the chemical inertness and stability of the polymer. Polytetrafluoroethylene also has excellent thermal stability and can be used at temperatures up to 250°C.

More than 5,000,000 clinical implants of GORE-TEX® ePTFE Medical Products in vascular, cardiac, dural, facial reconstructive, dental and a broad variety of general surgery applications during the past two decades have established a substantial body of knowledge and experience relating to the biocompatibility of ePTFE. A selected bibliography is provided in **Section 10**.

The GORE ReVox Thyroplasty Implant is provided sterile in a variety of sizes specifically configured for this indication. The applicant device, GORE ReVox Thyroplasty Implant, and its cited predicate devices have the same intended uses and their substantial equivalence is established in **Section 5**.

5. Intended Use:

The GORE ReVox Thyroplasty Implant is indicated for medialization thyroplasty in patients with unilateral vocal cord paralysis (UVCP) to improve voice quality. This is the same indication as both the VoCoM® System and the Montgomery® Thyroplasty Implant.

6. Technological Characteristics:

A literature review of the recent two decades indicates that the etiology of UVCP reveals two primary causes, neoplasm and surgical trauma. GORE ReVox Thyroplasty Implant is designed to be implanted utilizing current surgical techniques and standard surgical instruments in order to minimize surgeon “retraining”. Polytetrafluoroethylene has been used in laryngoplasty procedures since the 1960s, and other treatment modalities include insertion of fat grafts, hydroxylapatite, Gelfoam, blocks of Silastic® and GORE-TEX® ePTFE grafts.

The predicate devices fulfill their equivalent clinical functions by providing clinicians with a space-filling biomaterial, which medializes the paralyzed vocal cord. GORE-TEX® ePTFE products have been used safely and effectively as space-filling products in facial plastic and reconstructive applications for the past decade with no known adverse reactions attributable to the product. The microstructure of the applicant product is optimized to provide for surrounding native tissue attachment, while still allowing for device removal if revision or further augmentation is required.

GORE-TEX® and GORE are registered trademarks of W.L. Gore & Associates
Montgomery* Thyroplasty Implant is a registered trademark of Boston Medical Products, Inc.
Silastic* is a registered trademark of Dow Corning Corporation
VoCoM* is a registered trademark of Smith & Nephew Richards, Inc.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850W.L. Gore & Associates, Inc.
C/O John W. Nicholson
Regulatory Affairs Associate
3750 W. Kiltie Lane
P.O. Box 900
Flagstaff, AZ 86002Re: K983525
Gore ReVox Throplasty Implant
Dated: October 7, 1998
Received: October 8, 1998
Regulatory class: II
21 CFR 874.3620/Procode: 77 MIX

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 requirements, 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) 594-4613. 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" (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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983525

Device Name: GORE ReVox Thyroplasty Implant

Indications For Use:

For medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Geyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983525

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use