3/15/99

K984534

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: December 18, 1998

2. **Applicant Device:**

Trade Name: PRECLUDE® ACUSEAL Dura Substitute
Common Name: Dura Substitute

3. **Substantially Equivalent Devices:**

GORE cites the following as predicate devices to which the applicant device will be shown to be substantially equivalent:

- W.L. Gore & Associates, Inc. - PRECLUDE® Dura Substitute
- Dow Corning - Silastic® Reinforced Sheeting
- Bio-Vascular Inc. - DuraGuard®
- Aesculap Inc.- Neuro-Patch

4. **Device Description:**

The PRECLUDE ACUSEAL Dura Substitute is composed of expanded polytetrafluoroethylene (ePTFE) and an amorphous fluoropolymer (PATT) layer positioned within the plane of the device. This device is intended to be used for temporary or permanent repair of dura mater during neurosurgery.

Widely regarded as an inert biomaterial, ePTFE has established a successful clinical history of use in cardiac, vascular, dural, dental and a broad range of general surgical applications for more than two decades. The expanded PTFE portion of the device which contacts the cranial soft tissue structures is essentially unchanged; the proposed modification simply entails the interposition of a PATT material between the ePTFE components. The PATT component's industrial counterparts, perfluorelastomers, have a long history of commercial applications and the PATT material in the applicant device has successfully undergone an extensive array of biocompatibility evaluations. The PATT component material has also been thoroughly reviewed by CDRH's Office of Science and Technology and MAF-1024 has been developed. The PRECLUDE® ACUSEAL Dura Substitute is provided sterile in the same configurations as the predicate GORE device. It is intended for dural repair applications and is resterilizable.

5. Intended Use:

The PRECLUDE ACUSEAL Dura Substitute is intended for use as a temporary or permanent prosthesis for repair of dura mater during neurosurgery. The labeling reveals that the applicant and all predicate devices have the same intended use as dura substitute prostheses. Like the predicate devices, the PRECLUDE ACUSEAL Dura Substitute is intended for use in both cranial and spinal dura repair applications.

6. Technological Characteristics:

More than 5,000,000 clinical implants of GORE-TEX® Medical Products in a diverse array of biological environments have served to substantiate the safety and efficacy of these devices. The technical, preclinical, biocompatibility, descriptive and performance data in this Premarket Notification demonstrate that the applicant device is substantially equivalent to its cited predicate devices and that it is safe and effective for its intended use.

The biocompatibility data included in this submission reveal that the PRECLUDE® ACUSEAL Dura Substitute possesses the requisite characteristics to function safely in its intended uses. The *in vivo* animal testing demonstrates that the applicant device functions

safely and effectively as a dura substitute. The mechanical strength data and numerous comparative studies indicate that the applicant device performs in a substantially equivalent manner when compared to its cited predicates.

The clinical experience with more than 40,000 dural implants during the past decade demonstrates that the PRECLUDE® Dura Substitute device performs safely and effectively as a dura substitute. Male and female patients, as well as adults and children, were involved in clinical series assessing this device in cranial and spinal dural repair applications, and there were no known adverse reactions. The clinical data collected demonstrate that the device has the necessary structural, biocompatibility and biomechanical characteristics to function effectively as a dura substitute.

® PRECLUDE is a registered trademark of W.L. Gore & Associates
DuraGuard® is a registered trademark of Bio-Vascular, Inc.
Neuro-Patch is a trademark of B. Braun Melsungen AG
Silastic® is a registered trademark of Dow Corning Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Mr. John W. Nicholson
Regulatory Affairs
W. L. Gore & Associates, Inc.
3750 West Kiltie Lane
Flagstaff, Arizona 86002

Re: K984534
Trade Name: PRECLUDE® ACUSEAL Dura Substitute
Regulatory Class: II
Product Code: GXQ
Dated: December 18, 1998
Received: December 21, 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,

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): K984534

DEVICE NAME: PRECLUDE ACUSEAL Dura Substitute

INDICATIONS FOR USE:

For use as a temporary or permanent prosthesis for repair of dura mater during neurosurgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984534