K021477



## III. Summary of Information Regarding Safety & Effectiveness

NOV 8 2002

**Applicant:**

WL Gore & Associates, Inc.
3450 West Kiltie Lane
P. O. Box 500
Flagstaff, AZ 86002-0500

**Contact:**

Mike Johnson
Regulatory Affairs Associate

**Date Prepared:**

October 28, 2002

**Trade or Proprietary Name:**

PRECLUDE® MVP Dura Substitute

**Common or Usual Name:**

Dura Substitute

**Classification Name:**

Dura Substitute

**Device Predicates:**

- WL Gore & Associates, Inc. – PRECLUDE® ACUSEAL Dura Substitute (K984534)
- WL Gore & Associates, Inc. – PRECLUDE® Dura Substitute (K953969)
- WL Gore & Associates, Inc. – SEAMGUARD Staple Line Reinforcement Material (K010936)
- Integra Life Sciences Corp. – DuraGen Dural Graft Matrix (K982180)

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**Device Description:**

The applicant PRECLUDE® MVP Dura Substitute includes substantially equivalent materials and designs as the predicate PRECLUDE® Dura Substitute devices. The microstructure on the dural side of the applicant device is slightly altered to permit enhanced biological fixation and sealing. The neural side of the material is unchanged from the predicate PRECLUDE® Dura Substitutes. Side orientation is rendered apparent to the surgeon by means of texturing the open microstructure side with a visually and tactilely distinct "ridges and valleys" or "corduroy" pattern.

**Statement of Intended Use:**

The PRECLUDE® MVP Dura Substitute is intended for use as a temporary or permanent prosthesis for repair of dura mater during neurosurgery.

**Substantial Equivalence:**

A variety of tests, assessments, and comparisons demonstrate that the PRECLUDE® MVP Dura Substitute is substantially equivalent to the cited predicate devices in terms of composition, design, intended use, and performance attributes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Mr. Timothy J. Rynn
Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 West Kiltie Lane
Flagstaff, Arizona 86002-0500

Re: K021477
Trade/Device Name: Preclude® MVP Dura Substitute
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: August 14, 2002
Received: August 15, 2002

Dear Mr. Rynn:

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) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021477

## III. Statement of Intended Use



510(k) Number (if known) _____

**Device Name:** PRECLUDE® MVP Dura Substitute

**INDICATIONS FOR USE:**

The PRECLUDE® MVP Dura Substitute is intended 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 OR Over-The-Counter Use ___
(per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021477