

DEC 7 2005

## Premarket Notification 510(k) Summary

**Applicant:**

W.L. Gore and Associates Inc.  
3250 W. Kiltie Lane  
Flagstaff, AZ 86001

**Contact:**

Michael E. Ivey

**Date Prepared:**

November 15, 2005

**Trade or Proprietary Name:**

SEAMGUARD<sup>®</sup> Staple Line Reinforcement Material

**Common or Usual Name:**

Staple Line Reinforcement Material

**Classification**

21 CFR 878.3300, FTL

**Device Predicate:**

SEAMGUARD<sup>®</sup> Staple Line Reinforcement Material – K043056

**Device Description:**

The GORE SEAMGUARD<sup>®</sup> Bioabsorbable Staple Line Reinforcement Material for open staplers consists of a bioabsorbable membrane composed of a microporous structure of synthetic bioabsorbable glycolide and trimethylene carbonate copolymer. The GORE SEAMGUARD<sup>®</sup> Bioabsorbable Staple Line Reinforcement Material is to be used with surgical stapling devices.

The GORE SEAMGUARD<sup>®</sup> Bioabsorbable Staple Line Reinforcement Material is supplied in sterile polyethylene terephthalate / polyethylene pouches. These pouches contain the necessary material for the cartridge jaw and the anvil jaw of the surgical stapler.

**Statement of Intended Use:**

GORE SEAMGUARD<sup>®</sup> Bioabsorbable Staple Line Reinforcement Material is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE SEAMGUARD<sup>®</sup> Bioabsorbable Staple Line Reinforcement Material can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures. GORE SEAMGUARD<sup>®</sup> Bioabsorbable Staple Line Reinforcement Material is also intended to be used for reinforcement of suture-lines and staple-lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

**Substantial Equivalence:**

A variety of tests, assessments, and comparisons demonstrate that the SEAMGUARD<sup>®</sup> Staple Line Reinforcement Material for Open Staplers is substantially equivalent to its predicate in terms of composition, design, intended use, mode of operation and performance attributes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 7 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Michael Ivey  
Regulatory Affairs  
Medical Products Division  
W. L. Gore & Associates, Inc.  
3450 West Kiltie Lane  
Flagstaff, Arizona 86003-2400

Re: K053202

Trade/Device Name: GORE SEAMGUARD® Staple Line Reinforcement  
Material for Open Staplers

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: II

Product Code: FTL

Dated: November 15, 2005

Received: November 16, 2005

Dear Mr. Ivey:

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), 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Barbara Melkerson" with a small "for" written below the name.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K053202

Device Name: GORE SEAMGUARD® Staple Line Reinforcement Material  
for Open Staplers

## Indications for Use:

The GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures. GORE SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material is also intended to be used for reinforcement of suture-lines and staple-lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE) *[Signature]*  
**Division of General, Restorative  
and Neurological Devices**