DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 30, 2015

W.L. Gore and Associates Incorporated
Ms. Barbara L. Smith, RAC
Regulatory Associate
301 Airport Road, P.O. Box 1408
Elkton, Maryland 21921

Re: K150551
Trade/Device Name: GORE® SEAMGUARD® Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXC
Dated: March 10, 2015
Received: March 12, 2015

Dear Ms. Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150551

Device Name

GORE® SEAMGUARD® Reinforcement

Indications for Use *(Describe)*

GORE® SEAMGUARD® Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE® SEAMGUARD® Reinforcement 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® Reinforcement is also intended to be used for reinforcement of staple lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 – 510(k) Summary

510(k) Submitter

W. L. Gore & Associates, Inc.
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Elkton, Maryland 21921
Regulatory contact: Barbara L. Smith
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Date Prepared

March 30, 2015

Device Names/Classification

Trade Name:	GORE® SEAMGUARD® Reinforcement
Common Name:	Staple line reinforcement material
Classification Name:	Mesh, Surgical, absorbable, staple line reinforcement (21CFR878.3300)
Product Code:	OXC

Predicate Device

- K131658 GORE® SEAMGUARD® Reinforcement

Device Description

The modified GORE® SEAMGUARD® Reinforcement possesses the same indications for use and fundamental scientific technology as the predicate GORE® SEAMGUARD® Reinforcement. The implantable device and loading carriers of the predicate GORE® SEAMGUARD® Reinforcement are being modified to permit the reinforcement material to be loaded onto the stapler and attach via adhesive-coated tabs that wrap around the side/back of the cartridge/anvil jaws of a surgical stapling device, in lieu of attaching a fully-coated device surface to the top surfaces of the cartridge/anvil jaws, to minimize the impact of the surface topography of surgical staplers in establishing compatible device fit. The implantable materials of the modified GORE® SEAMGUARD® Reinforcement and predicate GORE® SEAMGUARD® Reinforcement are the same bioabsorbable PGA:TMC. Both utilize

the same bioabsorbable PLA:TMC adhesive to secure the device onto the jaws of a surgical stapler.

Indications for Use

GORE® SEAMGUARD® Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE® SEAMGUARD® Reinforcement 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® Reinforcement is also intended to be used for reinforcement of staple lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Summary of Similarities and Differences in Technological Characteristics

The indications for use for the modified GORE® SEAMGUARD® Reinforcement device is identical to the predicate GORE® SEAMGUARD® Reinforcement device. Both the modified and predicate GORE® SEAMGUARD® Reinforcement devices utilize loading carriers to load the implantable device and the same adhesive to secure the device onto the cartridge/anvil jaws of a compatible stapler. Both devices are comprised of the same bioabsorbable materials. The primary difference between the modified GORE® SEAMGUARD® Reinforcement and predicate GORE® SEAMGUARD® Reinforcement devices is the addition of adhesive-coated tabs for the modified device to permit attachment to a different location on a surgical stapler and a corresponding modification to the geometry of the loading carriers to facilitate attachment of the modified device.

Performance Data / Predicate Device Comparison

Pre-Clinical:

Bench study - Design verification testing of the modified GORE® SEAMGUARD® Reinforcement device consisted of deployment reliability testing under simulated use conditions and same/similar acceptance criteria. The tests demonstrated the performance of the modified GORE® SEAMGUARD® Reinforcement device is substantially equivalent to the predicate GORE® SEAMGUARD® Reinforcement device.

In Vivo (Animal study): No new animal studies were required to demonstrate substantial equivalence of the modified GORE® SEAMGUARD® Reinforcement device to the PREDICATE Seamguard. The animal studies conducted for the predicate GORE® SEAMGUARD® Reinforcement are applicable to the modified GORE® SEAMGUARD® Reinforcement device.

Clinical: No clinical evaluations of this product have been conducted.

Section 5 – 510(k) Summary

Conclusion

W.L. Gore & Associates concludes that the modified GORE® SEAMGUARD® Reinforcement device is *substantially equivalent* to the predicate GORE® SEAMGUARD® Reinforcement device in terms of indications for use, design, materials, biocompatibility, packaging, sterilization, labeling, and performance.