August 17, 2018

W. L. Gore & Associates, Inc.
Michael J. Titus, Ph.D.
Regulatory Affairs Associate
301 Airport Road
Elkton, Maryland 21922

Re: K181940
Trade/Device Name: GORE SEAMGUARD Bioabsorbable Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXC
Dated: July 17, 2018
Received: July 19, 2018

Dear Dr. Titus:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181940

Device Name

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement

Indications for Use *(Describe)*

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. It 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. It 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6 - 510(k) Summary [21 CFR 807.92]

510(k) Submitter

W. L. Gore & Associates, Inc.
301 Airport Road
Elkton, Maryland 21921
Regulatory contact: Michael J. Titus, Ph.D.

Date Prepared

July 30, 2018

Device Names/Classification

Device Name:	GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement
Common Name:	Staple Line Reinforcement Material
Classification Name:	Surgical mesh
Classification:	21CFR 878.3300
Product Code:	OXC

Predicate Devices

K043056 GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement

Device Description

The subject of this 510(k) pre-market notification is a modification to the GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material Configured for Endoscopic Surgical Staplers (EBSG, also referred to as the predicate) to include altered bioabsorbable sheet geometries, tailored lattice stitching, and inner dimension geometry for both the cartridge and anvil devices. The cartridge and anvil devices were specifically designed to fit the geometry of the Intuitive SureForm 60™ mm staplers (**K173721** cleared July 5, 2018) Black, Green and Blue cartridge reloads. GORE® SEAMGUARD® Reinforcement Bioabsorbable Staple Line Reinforcement Configured for Intuitive Surgical® Robotic Endoscopic Surgical Staplers (EBSG-R, also referred to as the modified device) possesses the same fundamental scientific technology as the predicate. No other physical modifications were made to the predicate device, and the implantable materials of the modified device and predicate are the same synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer (PGA:TMC).

Indications for Use

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. It 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. It 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.

Differences in Technological Characteristics

There are no technological differences between the modified device and the predicate device.

Summary of Performance Testing

Pre-Clinical

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

In Vivo (Animal study): No changes were made to device function, technology or component materials, and no indications were added, therefore, no new animal studies were needed to demonstrate substantial equivalence of the EBSG-R device to the predicate EBSG device.

Clinical

No clinical evaluations were required to support this submission.

Conclusion

Based on the information contained within this 510(k) premarket notification, W. L. Gore & Associates, Inc. concludes that the subject device GORE® SEAMGUARD® Reinforcement Bioabsorbable Staple Line Reinforcement Configured for Intuitive Surgical® Robotic Endoscopic Surgical Staplers is substantially equivalent to the predicate device in terms of indications for use, contraindications, construct, materials, biocompatibility, sterilization, and performance.