July 31, 2019

W.L. Gore & Associates, Inc.
Barbara Smith
Regulatory Associate
301 Airport Road
Elkton, Maryland 21921

Re: K191773
Trade/Device Name: GORE BIO-A Tissue Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OWZ, OXC, OXF
Dated: June 28, 2019
Received: July 2, 2019

Dear Barbara 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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)*

K191773

Device Name

GORE® BIO-A® Tissue Reinforcement

Indications for Use *(Describe)*

GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. This includes use in patients requiring soft tissue reinforcement in plastic and reconstructive surgery.

Examples of applications where GORE® BIO-A® Tissue Reinforcement may be used include:
-Hernia repair as suture line reinforcement
-Muscle flap reinforcement
-General tissue reconstructions

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510(K) SUMMARY

510(k) Submitter

W. L. Gore & Associates, Inc.
301 Airport Road
Elkton, Maryland 21921
Regulatory contact: Barbara L. Smith, RAC
Phone: 410-506-8189
E-mail: blsmith@wlgore.com

Date Prepared

June 28, 2019

Device Names/Classification

Device Name:	GORE® BIO-A® Tissue Reinforcement
Classification Name:	Mesh, surgical, polymeric
Regulation:	21CFR 878.3300
Classification:	Class II
Product Code:	OWT, OWZ, OXC, OXF

Predicate Devices

- K163217 GORE® BIO-A® Tissue Reinforcement

Device Description

The subject GORE® BIO-A® Tissue Reinforcement is a bioabsorbable web structure that functions as a surgical mesh for soft tissue reinforcement while providing a scaffold for tissue ingrowth. It is used to reinforce soft tissue during the phases of wound healing by filling soft tissue deficits. The device elicits a physiologic tissue response which fills the deficit with native tissue and gradually absorbs the device. The implanted GORE® BIO-A® Tissue Reinforcement is a textured porous fibrous web surface on both surfaces composed solely of synthetic bioabsorbable poly (glycolide:trimethylene carbonate) copolymer (PGA:TMC). In vivo studies with this copolymer indicate the bioabsorption process should be complete by six to seven months. The GORE® BIO-A® Tissue Reinforcement is available in various sizes and can be trimmed to the desired shape by the surgeon at time of use. The device is sterilized by gamma irradiation validated to an SAL of 10^{-6}. It is for single use only.

Indications for Use
GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. This includes use in patients requiring soft tissue reinforcement in plastic and reconstructive surgery.

Examples of applications where GORE® BIO-A® Tissue Reinforcement may be used include:
-Hernia repair as suture line reinforcement
-Muscle flap reinforcement
-General tissue reconstructions

Differences in Technological Characteristics

The subject of this 510(k) is a labeling change that is not related to any safety or effectiveness issue for the GORE® BIO-A® Tissue Reinforcement. There are no differences in technological characteristics between the subject and predicate device.

Summary of Performance Testing

No bench, animal, or clinical studies were required to support the labeling modification.

Conclusion

The GORE® BIO-A® Tissue Reinforcement device is substantially equivalent to the predicate devices in terms of indications for use, design, materials, biocompatibility, sterilization, packaging, and labeling.