April 5, 2018

W.L. Gore & Associates, Inc.
Barbara Smith
Regulatory Associate
1505 N. Fourth Street
Flagstaff, Arizona 86004

Re: K173333
Trade/Device Name: GORE ENFORM Biomaterial
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXF, OXC, OWT, OWZ
Dated: October 20, 2017
Received: October 23, 2017

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -S3

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)*
K173333

Device Name
GORE® ENFORM Biomaterial

Indications for Use *(Describe)*
GORE® ENFORM Biomaterial is indicated 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® ENFORM Biomaterial may be used include hernia repair as suture line reinforcement, muscle flap reinforcement, and 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.

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Section 5 - 510(k) Summary

510(k) Submitter

W. L. Gore & Associates, Inc.
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E-mail: blsmith@wlgore.com

Date Prepared

October 20, 2017

Device Names/Classification

Device Name:	GORE® ENFORM Biomaterial
Classification Name:	Mesh, surgical, polymeric
Regulation:	21CFR 878.3300
Classification:	Class II
Product Code:	OXF, *OWT,* OWZ, OXC

Predicate Devices

- K163217 GORE® BIO-A® Tissue Reinforcement
- K152609 GORE® SYNECOR Intraperitoneal Biomaterial
- K143380 BARD® Phasix™ ST Mesh

Device Description

As packaged, GORE® ENFORM Biomaterial is a porous, three-dimensional sheet comprised of a bioabsorbable PGA:TMC copolymer in a matrix (scaffold) structure that functions to reinforce soft tissue during the phases of wound healing by filling soft-tissue deficits. The bioabsorbable, porous scaffold structure of the ENFORM device elicits a physiological response which fills the deficit with native tissue and gradually absorbs the device. There are two configurations of the GORE® ENFORM Biomaterial. One configuration will possess an added PGA:TMC film layer on one side of the device to provide visceral protection in soft tissue reinforcement applications requiring intraperitoneal contact with the viscera. Both ENFORM configurations are available in various sizes and can be trimmed to the desired shape by the surgeon at time of use. The GORE® ENFORM Biomaterial is supplied sterile for single use only.

Section 5 - 510(k) Summary

Indications for Use

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Differences in Technological Characteristics

The GORE® ENFORM Biomaterial with film configuration, a fully absorbable device, contains a visceral protection film layer not present in the predicate GORE® BIO-A® Tissue Reinforcement. However, the GORE® SYNECOR Intraperitoneal predicate possesses a visceral protection film comprised of the same material as the GORE® ENFORM Biomaterial with film. (The permanent PTFE knit middle layer of the predicate GORE® SYNECOR is not present in the GORE® ENFORM Biomaterial devices and therefore, was not compared.) The predicate PHASIX™ ST, also a fully absorbable device, possesses a visceral protection layer comprised of a different material (hydrogel barrier).

Summary of Performance Testing

Biocompatibility: Biocompatibility evaluation appropriate for a tissue contacting implant with permanent duration of exposure was conducted according to "*Use of International Standard /SO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Guidance for Industry and Food and Drug Administration Staff. June 16, 2016".*

Bench study: The bench testing conducted included but was not limited to evaluation of surgical manipulation, suture needle penetration, stiffness, tensile strength. Results demonstrated that both configurations of the GORE® ENFORM Biomaterial met the performance criteria established for the indicated uses of the device.

Animal study: Animal studies were conducted to compare the performance of the ENFORM Biomaterial to the predicate control devices with respect to visceral protection, tissue ingrowth and tissue response.

Conclusion

The information and test results contained within this 510(k) premarket notification demonstrate that the subject GORE® ENFORM Biomaterial device is substantially equivalent to the predicate devices in terms of indications for use, design, materials, biocompatibility, sterilization, packaging, and performance.