December 19, 2022

W. L. Gore and Associates, Inc.
Barbara Smith
RAc
301 Airport Road
Elkton, Maryland 21921

Re: K222919
Trade/Device Name: GORE® ENFORM Biomaterial
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXF, OWT, OWZ, OXC
Dated: September 23, 2022
Received: September 26, 2022

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,

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222919

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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510(K) SUMMARY

510(k) Submitter

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

Date Prepared: December 13, 2022

Device Names/Classification

Device Name: GORE® ENFORM Biomaterial

Classification Name: Mesh, Surgical, Polymeric

Regulation: 21CFR 878.3300 / Surgical Mesh

Classification: Class II

Product Code: OXF, OWT, OWZ, OXC

Predicate Devices

K173333 GORE® ENFORM Biomaterial

K152309 GORE® SYNECOR Intraperitoneal Biomaterial

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.

Indications for Use

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.

Differences in Technological Characteristics

There are no technological differences between the subject GORE® ENFORM Biomaterial device and the predicate GORE® ENFORM Biomaterial. The predicate GORE® SYNECOR Biomaterial device possesses an additional permanent PTFE layer not present in GORE® ENFORM Biomaterial device.

Summary of Performance Testing

Pre-Clinical

Bench

Simulated use testing conducted as part of design verification demonstrated the GORE® ENFORM Biomaterial devices can be introduced via minimally invasive surgical procedures when used according to the instructions for use of the device. Other bench testing was leveraged from the predicate GORE® ENFORM Biomaterial device. The update to the device labeling has no impact on biocompatibility since the subject GORE® ENFORM Biomaterial is identical in material and design to the predicate GORE® ENFORM Biomaterial device.

Animal

No animal studies were required to support this change.

Clinical

No clinical data was required to support this change.

Conclusion

While the predicate GORE® SYNECOR Biomaterial devices possesses a technological difference compared to the subject GORE® ENFORM Biomaterial device, the difference did not raise any new or different issues of safety and effectiveness when tested using methods consistent with the predicate GORE® SYNECOR Biomaterial device. Like the predicate GORE® SYNECOR Biomaterial, GORE® ENFORM Biomaterial demonstrated acceptable performance when used in simulated minimally invasive surgical procedures. W. L. Gore & Associates concludes the subject GORE® ENFORM Biomaterial is *substantially equivalent* to the predicate devices.