DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2017

W.L. Gore & Associates, Inc.
Ms. Barbara L. Smith, RAC
Regulatory Affairs
1505 N. Fourth Street
Flagstaff, AZ 86004

Re: K163217
Trade/Device Name: GORE BIO-A Tissue Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXF, OWT, OWZ, OXC
Dated: November 15, 2016
Received: November 16, 2016

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,

Jennifer R. Stevenson -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)*
K163217

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.

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510(k) Submitter

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

Date Prepared

November 15, 2016

Device Names/Classification

Device Name: GORE® BIO-A® Tissue Reinforcement

Classification Name: Mesh, surgical, polymeric

Classification: 21CFR878.3300

Product Code: OXF, OWT, OWZ, OXC

Predicate Devices

x	K034039	Cook SIS Plastic Surgery Matrix
x	K033671	Gore Bioabsorbable Mesh
x	K132025	MESO Bilayer Surgical Mesh

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. It 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 porous, fibrous flat sheet web structure composed solely of synthetic bioabsorbable polyglycolide / trimethylene carbonate copolymer. In vivo studies indicate the bioabsorption process should be complete by six to seven months. The device 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, and General tissue reconstructions

Differences in Technological Characteristics

The information provided in this premarket notification supports that the difference in material between the subject and predicate mesh devices (synthetic polymer vs. porcine tissue) raises no new issues of safety or effectiveness when used for the expanded indication in patients requiring soft tissue reinforcement in plastic and reconstructive surgery.

Summary of Performance Testing

No bench or clinical testing was used to support this 510(k) premarket notification. The animal study presented in this submission demonstrated equivalent performance when comparing Gore's synthetic PGA:TMC scaffold to a Cook's SIS collagen-based scaffold structure. The two materials performed as intended in an equivalent manner and raised no new questions of safety or effectiveness.

Conclusion

W. L. Gore & Associates concludes that the subject GORE® BIO-A® Tissue Reinforcement device is substantially equivalent to the predicate devices in terms of intended/indications for use, design, materials, function, biocompatibility, and sterilization.