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

May 11, 2017

W. L. Gore & Associates, Inc.
Mr. Michael Titus
Regulatory Associate
1505 N. Fourth Street
Flagstaff, Arizona 86004

Re: K163576
Trade/Device Name: Gore Synecor Preperitoneal Biomaterial
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 12, 2017
Received: April 13, 2017

Dear Mr. 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. 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" (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.

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163576

Device Name
GORE® SYNECOR PREPERITONEAL Biomaterial

Indications for Use *(Describe)*
GORE® SYNECOR PREPERITONEAL Biomaterial is intended for use in the repair of hernias and abdominal wall soft tissue deficiencies that may require the addition of non-absorbable reinforcing or bridging material.

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.

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510(K) SUMMARY [21 CFR 807.92]

510(k) Submitter

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Date Prepared

May 10, 2017

Device Names/Classification

Device Name: GORE® SYNECOR Preperitoneal Biomaterial

Common Name: Mesh, surgical, polymeric

Classification Name: Surgical Mesh

Classification: 21CFR 878.3300 Product

Code: FTL

Predicate Devices

K152609 GORE® SYNECOR Biomaterial

Device Description

GORE® SYNECOR Preperitoneal Biomaterial is a composite mesh intended for use in the repair of hernias and abdominal wall soft tissue deficiencies that may require the addition of non-absorbable reinforcing or bridging material. The device incorporates two distinct functional layers comprised of 1) a polytetrafluoroethylene (PTFE) knit mesh, laminated between 2) two porous synthetic bioabsorbable web layers. The permanent PTFE knit layer functions to provide strength when bridging a hernia or soft tissue defect. The porous bioabsorbable web layers provide a scaffold for tissue ingrowth and vascularization. The GORE® SYNECOR Preperitoneal Biomaterial is for

single use only and is designed for preperitoneal placement and should be placed between tissue layers where ingrowth is desired.

Indications for Use

GORE® SYNECOR Preperitoneal Biomaterial is intended for use in the repair of hernias and abdominal wall soft tissue deficiencies that may require the addition of non-absorbable reinforcing or bridging material.

Differences in Technological Characteristics

Materials of construction are identical for the two devices but the GORE® SYNECOR Preperitoneal Biomaterial possesses two PGA/TMC porous web layers and no PGA/TMC film layer. The predicate device, GORE® SYNECOR Biomaterial, has one PGA/TMC porous web layer along with a PGA/TMC film layer. This PGA/TMC porous web layer is composed of the same materials that comprise the previously cleared GORE® BIO-A Tissue Reinforcement. Relative to the GORE® BIO-A Tissue Reinforcement device, the PTFE mesh knit is unique to the SYNECOR devices as an additional material, and as an implanted material. Substantial equivalence of the packaging components and the initial shelf life data were based on the predicate device testing.

Summary of Performance Testing

Pre-Clinical

Bench study: Testing demonstrated the GORE® SYNECOR Preperitoneal Biomaterial device met the intended functional acceptance criteria necessary for providing strength when bridging a hernia or soft tissue defect for up to the stated shelf life. Performance data includes acceptable results for mesh thickness, density, suture retention, burst strength, and pore size relative to the predicate device. The three year shelf life is supported by the known stability of PTFE, and real time data correlated with accelerated aging data for the predicate surgical mesh device, GORE® BIO-A Tissue Reinforcement. This reference device is made of the same PGA/TMC copolymer and has similar physical and chemical properties as the bioresorbable component of GORE® SYNECOR Preperitoneal Biomaterial.

Biocompatibility: While the GORE® SYNECOR Preperitoneal Biomaterial device is composed of materials (i.e., PTFE, PGA, TMC) that have long-standing histories of safe clinical use, GORE has demonstrated that these materials are biocompatible in the manufacture of GORE® SYNECOR Preperitoneal Biomaterial device by conducting an extensive battery of standardized *in vitro* and *in vivo* tests according to ISO 10993 standards, including cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, rabbit pyrogen, genotoxicity, local effects after implantation and subchronic toxicity.

Animal study: The subject GORE® SYNECOR Preperitoneal Biomaterial was studied in a 30 day subcutaneous implant rabbit model while the predicate

device, GORE® SYNECOR Biomaterial, was studied in an intraperitoneal implant rabbit model, under a separate protocol. Overall, the tissue response was similar for these constructs with the presence of organized, vascularized collagenous tissue ingrowth within the web and filling the macropores. Furthermore, the inflammatory response was as expected for a resorbable medical device in both cellular make-up and extent. Additionally, a 90 day rat subchronic toxicity study per ISO 10993 involving multiple device implants resulted in no noteworthy systemic toxicity. Finally, a 180 day subcutaneous implant study in rabbits compared the subject device against the Ethicon Physiomesh® device with an overall tissue response typical for these types of constructs.

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 concludes that the subject GORE® SYNECOR Preperitoneal Biomaterial device is substantially equivalent to the predicate device in terms of indications for use, contraindications, construct, materials, biocompatibility, sterilization, and performance.