



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

December 11, 2015

W.L. Gore & Associates Incorporated  
Ms. Barbara Smith  
Official Correspondent  
301 Airport Road  
Elkton, Maryland 21921

Re: K152609  
Trade/Device Name: GORE SYNECOR Biomaterial  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: Class II  
Product Code: FTL  
Dated: September 11, 2015  
Received: September 14, 2015

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" (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 yours,

**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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)  
K152609

Device Name

GORE SYNECOR Biomaterial

Indications for Use (Describe)

The GORE SYNECOR Biomaterial device is intended for use in the repair of hernias and abdominal wall or thoracic wall soft tissue deficiencies that may require the addition of a 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.**

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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**510(k) Submitter**

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**Date Prepared**

September 9, 2015

**Device Names/Classification**

Device Name: GORE® SYNECOR Biomaterial

Classification Name: Mesh, surgical, polymeric

Classification: 21CFR878.3300

Product Code: FTL

**Predicate Devices**

- K093932 ETHICON PHYSIOMESH® Flexible Composite Mesh
- K081069 GORE® INFINIT® Mesh
- K033671 GORE® BIO-A® Tissue Reinforcement

**Device Description**

GORE® SYNECOR Biomaterial is a composite mesh intended for use in the repair of hernias and abdominal wall or thoracic wall soft tissue deficiencies that may require the addition of non-absorbable reinforcing or bridging material. The device incorporates three distinct functional layers comprised of 1) a polytetrafluoroethylene (PTFE) knit mesh, laminated between 2) a non-porous synthetic bioabsorbable PGA:TMC film layer, and 3) a porous synthetic bioabsorbable PGA:TMC web layer. The permanent PTFE knit layer functions to provide strength when bridging a hernia or soft tissue defect. The non-porous bioabsorbable film layer is designed to limit cellular penetration which serves to minimize visceral adhesion formation to the material. The porous bioabsorbable web layer provides a scaffold for cellular infiltration and vascularization. The GORE® SYNECOR Biomaterial is for single use only.

## **Indications for Use**

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

## **Differences in Technological Characteristics**

The GORE® SYNECOR Biomaterial possesses a film layer not present in the Gore predicate devices. The primary difference between the subject GORE® SYNECOR Biomaterial device and predicate composite PHYSIOMESH is in the constituent materials.

## **Summary of Performance Testing**

### Pre-Clinical

Bench study: Testing demonstrated the GORE® SYNECOR 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. Suture retention and burst strength testing was also performed to compare the GORE® SYNECOR Biomaterial to the predicate devices.

Animal study: The subject GORE® SYNECOR Biomaterial and predicate composite (control) device were studied in a rabbit model. The results demonstrated that the GORE® SYNECOR Biomaterial had no midsurface adhesions similar to the control (predicate) device. Furthermore, there was no statistical difference in the amount of fibrous tissue ingrowth for the GORE® SYNECOR Biomaterial relative to the predicate. Overall histopathology was as expected for the type and construction of both devices with organized tissue ingrowth and vascularity filling the macropores.

### Clinical

No clinical evaluations of this product have been conducted.

## **Conclusion**

Based on the information contained within this 510(k) premarket notification, W. L. Gore & Associates concludes that the subject GORE® SYNECOR Biomaterial device is substantially equivalent to the predicate devices in terms of indications for use, contraindications, construct, materials, biocompatibility, sterilization, and performance.