December 15, 2017

Boston Scientific Corporation
Elizabeth Renken
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K171271
Trade/Device Name: Polyform™ Synthetic Mesh
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTO
Dated: November 10, 2017
Received: November 15, 2017

Dear Elizabeth Renken:

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K171271

Device Name
Polyform™ Synthetic Mesh

Indications for Use *(Describe)*
Polyform Synthetic Mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

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) Summary for Polyform™ Synthetic Mesh

K171271

Date of Summary: December 14, 2017

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01752

B. Contact

Elizabeth Renken
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Or

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C. Device Information

Trade name:	Polyform™ Synthetic Mesh
Common/usual name:	Surgical Mesh
Classification Name:	Surgical Mesh (21 CFR 878.3300)
Class:	II
Product Code:	OTO – Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal and Uterine Prolapse, Trasabdominally Placed
Predicate:	Polyform™ Synthetic Mesh (K051245)

The predicate device has not been subject to a design related recall.

E. Device Description

The subject device consists of monofilament polypropylene fibers knitted into a sheet. It is rectangular in shape and available in two sizes, 10 x 15 cm and 15 x 20 cm. Surgeons implanting the subject device cut the mesh to the size and shape needed for an individual patient. The subject device is single use only, supplied sterile, and individually packaged in a Tyvek/Mylar pouch. The subject and predicate device are identical.

F. Indications for Use

Polyform Synthetic Mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

The subject and predicate device have the same intended use.

G. Technological Characteristics

The subject and predicate device are identical; and accordingly, they have the same technological characteristics.

H. Performance Summary

The Polyform Synthetic Mesh submitted herein is a modification of the predicate mesh device, Polyform Synthetic Mesh (K051245). The modification is an update to the device instructions for use packaged with the product. No performance data are needed to support the modifications to the instructions for use.

I. Substantial Equivalence

The proposed Polyform Synthetic Mesh is substantially equivalent to the predicate device.