September 26, 2019

Exogenesis Corporation
℅ Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K191545
Trade/Device Name: Exogenesis Hernia Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: June 10, 2019
Received: June 11, 2019

Dear Ms. O'Connell:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191545

Device Name
Exogenesis Hernia Mesh

Indications for Use *(Describe)*
The Exogenesis Hernia Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of reinforcing material to obtain the desired surgical result. The Exogenesis Hernia Mesh is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect). The Exogenesis Hernia Mesh is not indicated for transvaginal pelvic organ prolapse repair.

The Exogenesis Hernia Mesh is intended for single patient one-time use only.

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

Exogenesis Hernia Mesh

Submitter: Exogenesis Corporation
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Billerica, MA 01821

978-439-0120

Contact Person: Maureen O'Connell
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Phone: 978-207-1245

Date Prepared: September 18, 2019

Trade Name: Exogenesis Hernia Mesh

Classification Name: Surgical Mesh

Regulation Number: 21 CFR 878.3300

Product Code: FTL

Predicate Device: Ethicon, Inc. Prolene Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh – K180829

Device Description: The Exogenesis Hernia Mesh is a sterile prosthesis designed to provide mechanical support for reconstruction of soft tissue deficiencies. The device is intended for the repair of hernias and other fascial deficiencies requiring the addition of reinforcing or bridging material to obtain the desired surgical result. The Exogenesis Hernia Mesh is composed of knitted filaments of extruded polypropylene, and knitted to provide elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The Exogenesis Hernia Mesh is treated with a proprietary technology to modify the surface of the mesh to increase surface area of the filaments on a microscopic level.

Indications for Use:

The Exogenesis Hernia Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of reinforcing material to obtain the desired surgical result. The Exogenesis Hernia Mesh is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect). The Exogenesis Hernia Mesh is not indicated for transvaginal pelvic organ prolapse repair.

The Exogenesis Hernia Mesh is intended for single patient one-time use only.

Summary of Technological Characteristics:

The Exogenesis Hernia Mesh is constructed of polypropylene fibers warp knitted together to form the mesh. The knitting process creates a device with large pores and minimum density and thickness similar to the light weight meshes currently on the market. The result is an implant which allows tissue ingrowth that reinforces the tissue defect, while minimizing the inflammatory response and fibrous encapsulation related to implant mass. The mesh possesses the mechanical and physical properties necessary for long term tissue support. The Exogenesis Hernia Mesh is surface treated using a proprietary process to increase surface area of the filaments on a microscopic level.

Substantial Equivalence Discussion:

Exogenesis Corporation believes that the Exogenesis Hernia Mesh described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device. The following table presents the Exogenesis Hernia Mesh compared with the predicate device which is the Ethicon, Inc. Prolene Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh cleared in K180829.

Substantial Equivalence Comparison

Characteristic	Exogenesis Hernia Mesh	Prolene Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh
Manufacturer	**Exogenesis Corporation**	**Ethicon Inc.**
510(k) Number	**TBD**	**K180829**
Class	II	II
Device Classification Name	Mesh, Surgical, Polymeric	Mesh, Surgical, Polymeric
Regulation Number	878.3300	878.3300
Product Code	FTL	FTL
Use	Prescription	Prescription
Indications for Use	… is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of reinforcing material to obtain the desired surgical result. The Exogenesis Hernia Mesh is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect). The Exogenesis Hernia Mesh is not indicated for transvaginal pelvic organ prolapse repair. …is intended for single patient one-time use only.	..is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result. The PROLENE™ Hernia System is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect).
Device Composition	Polypropylene (non-resorbable)	Polypropylene (non-resorbable)
Construction	Knitted filaments of extruded polypropylene	Knitted filaments of extruded polypropylene
Bench Testing for Hernia Mesh	Pass	Pass
Animal Data	Yes	No
Biocompatibility	Biocompatible	Biocompatible
Sterile	Yes	Yes

Characteristic	Exogenesis Hernia Mesh	Prolene Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh
Single Use	Yes	Yes

The intended use of both the Exogenesis Hernia Mesh and the Prolene predicate device is as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue. The Exogenesis Hernia Mesh and the Prolene predicate device are both mesh devices composed of polypropylene which is non-resorbable. Both devices are made from knitted filaments of extruded polypropylene. Both devices are provided sterile and are for single use only. The Exogenesis Hernia Mesh has an additional processing step compared to the Prolene, which is Accelerated Neutral Atom Beam (ANAB) processing. This step does not add any new materials of construction and does not change the chemical composition of the product

Performance Testing

Biocompatibility testing has been performed on the final version of the Exogenesis Hernia Mesh which supports the substantial equivalence of the material including the processing. Performance testing is provided which compares the physical characteristics of the Exogenesis Hernia Mesh in both its untreated state and with processing as well as compared to the predicate device. There were no significant differences between the Exogenesis untreated Hernia Mesh and the Exogenesis processed Hernia Mesh in physical or mechanical parameters. These results confirm that the processing has no measurable impact on the structure and function of the polypropylene mesh and supports substantial equivalence.

In addition, there were no significant differences between the Exogenesis Hernia Mesh and the Prolene predicate device with respect to mesh thickness and single-fiber thickness. However, the pore size for the Exogenesis Hernia Mesh was greater than that of the predicate device. In performance testing, there were no differences between the Exogenesis Hernia Mesh and the Prolene predicate device in tear resistance. Given that Prolene is a stiffer mesh, it demonstrated higher tensile, suture pull-out and burst strength than the Exogenesis Hernia Mesh. However, published results for the Prolite Ultra showed that the Exogenesis mesh was higher than the ProLite Ultra. In addition, all meshes reported higher burst strength than that of abdominal muscle. The results of this testing confirm that the Exogenesis Hernia Mesh is substantially equivalent to the predicate device.

Additionally, animal testing was performed which assessed the localized tissue interaction and the mechanical properties of the untreated Exogenesis Hernia Mesh compared to the processed Exogenesis Hernia Mesh. Results at Day 90 and Day 180 showed that both versions of the Exogenesis Hernia Mesh were comparable in burst strength, and both were much greater in burst strength as compared to the native abdominal wall.

Therefore, biocompatibility testing and bench and animal testing support substantial equivalence.

Therefore, in summary, the new device has the same intended use and similar technological characteristics to the predicate device and is therefore, substantially equivalent. Performance data support substantial equivalence of the different technological characteristics.