October 22, 2019

Ethicon, Inc.
Melina Escobar
Regulatory Affairs Specialist II
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K191373
Trade/Device Name: VICRYL Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 22, 2019
Received: May 23, 2019

Dear Melina Escobar:

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,

For 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)*
K191373

Device Name
VICRYL Mesh

Indications for Use *(Describe)*
VICRYL Mesh may be used wherever temporary wound or organ support is required (kidney, liver, spleen). VICRYL Mesh may be cut to the shape or size desired for each specific application.

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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ETHICON
a Johnson & Johnson company

510(k) Summary

Submission Date: 10/23/2019

K191373

SUBMITTER INFORMATION:

Company Name: Ethicon, Inc. a Johnson & Johnson company

Company Address: P.O. Box 151
Route 22 West
Somerville, NJ 08876-0151

Contact Person: Melina Escobar
Regulatory Affairs Specialist II
Phone: 908-218-2583
Fax: 908-218-2595
Email: mescob14@its.jnj.com

Device Trade Name: VICRYL™ Mesh

Device Common Name: VICRYL™ Mesh

Class: Class II

Classification: 21 CFR 878.3300 – Surgical Mesh

Product Code: FTL

Predicate Devices:

Device	**Company**	**Product Code**	**510(k) Number**	**Predicate for**
VICRYL™ (Polyglactin 910) Mesh	Ethicon, Inc.	FTL	K810428	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics

Device	Company	Product Code	510(k) Number	Predicate for
VICRYL™ Mesh Bag	Ethicon, Inc.	FTL	K051701	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics

Device Description:

VICRYL™ (polyglactin 910) Mesh is a synthetic absorbable sterile copolymer made from glycolide and L-lactide. The copolymer is identical in composition to that used in VICRYL™ (polyglactin 910) synthetic absorbable suture.

VICRYL™ Knitted Mesh, which is more porous than VICRYL™ Woven Mesh, may be used in instances in which compliant and stretchable support material is desired.

Indications for Use:

VICRYL™ Mesh may be used wherever temporary wound or organ support is required (kidney, liver, spleen). VICRYL™ Mesh may be cut to the shape or size desired for each specific application.

Summary of Technological Characteristics:

VICRYL™ Mesh is substantially equivalent to the VICRYL™ Mesh (K810428) and VICRYL™ Mesh Bag (K051701) predicate devices with respect to technological characteristics. Both the subject and predicate devices are synthetic absorbable sterile copolymer. The devices function in the same manner and are designed to be used wherever temporary wound or organ support is required (kidney, liver, spleen). The subject mesh is manufactured within the existing manufacturing processes for the predicate device. There are no changes to the manufacturing, packaging, sterilization processes, or shelf life of the currently marketed device.

The subject VICRYL™ Mesh, for which this 510(k) Premarket Notification is being submitted, differs from the currently marketed device, K810428, in the labeling (Instructions for Use). The Instructions for Use has been revised to clarify the indications. Additionally, several other sections of the Instructions for Use of the subject devices have been reworded/ reformatted for clarity to address and align with evolving regulatory expectations.

Substantial Equivalence:

VICRYL™ Mesh is substantially equivalent to the VICRYL™ Mesh (K810428) and VICRYL™ Mesh Bag (K051701) predicate devices with respect to technological characteristics. Both the subject and predicate device are synthetic absorbable sterile copolymer. The devices function in the same manner and are designed to be used wherever temporary wound or organ support is required (kidney, liver, spleen). The subject mesh is manufactured within the existing manufacturing processes for the predicate device. There are no changes to the manufacturing, packaging, sterilization processes, or shelf life of the currently marketed device.

The subject VICRYL™ Mesh, for which this 510(k) Premarket Notification is being submitted, differs from the currently marketed device, K810428, in the labeling (Instructions for Use). The Instructions for Use has been revised to clarify the indications. Additionally, several other sections of the Instructions for Use of the subject devices have been reworded/ reformatted for clarity to address evolving regulatory expectations.

Conclusion:

VICRYL™ Mesh is substantially equivalent to the predicate devices, K810428 and K051701 in indications for use, fundamental scientific technology, and technological characteristics. It is as safe and effective as the predicates. Ethicon considers VICRYL™ Mesh to be substantially equivalent to the predicate devices.