September 28, 2018

Ethicon, Inc.
% Ms. Donna Marshall
Regulatory Affairs Manager
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K181652
Trade/Device Name: Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: August 30, 2018
Received: August 31, 2018

Dear Ms. Marshall:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181652

Device Name
Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorable Suture

Indications for Use *(Describe)*
Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorbable Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

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, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon Inc. a Johnson & Johnson company
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USA

Contact Person: Donna Marshall
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Date Prepared: September 26, 2018

Device Trade Name:	Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Synthetic Absorbable Suture
Device Common Name:	Suture, Surgical, Absorbable
Class:	II
Classification Name:	Absorbable Poly(glycolide/L-lactide) Surgical Suture (21 CFR 878.4493)
Product Code:	GAM
Panel:	General and Plastic Surgery Devices

Predicate Device:

Device Trade Name	510(k) Number
Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorable Suture	K132580

Device Description:

Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorbable Suture is a sterile, synthetic absorbable surgical suture (dyed and undyed) and is composed of a copolymer made from 90% glycolide and 10% L-lactide. Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorbable Suture is coated with a mixture composed of equal parts of a copolymer of glycolide and lactide (Polyglactin 370) and calcium stearate. The suture contains IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 472 µg/m. The copolymers in

the product have been found to be nonantigenic, nonpyrogenic and elicit only a mild tissue reaction during absorption. The suture is available undyed(natural) or dyed (D&C Violet No. 2).

Indications for Use:

Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorbable Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

Performance Data:

The technological characteristics of the proposed device is identical to the predicate device, therefore, performance data are not necessary to establish substantial equivalence.

Substantial Equivalence:

The subject device is identical to the predicate device with respect to functionality, technological characteristics and intended use. There is no material, device construction, performance specification, packaging, sterilization or manufacturing process changes to the currently marketed devices. The device differs only in the labeling (Instructions for Use) that have been revised to include the references of the latest publication of meta-analysis and guidelines for consideration of the use of triclosan-coated sutures to lower surgical site infection rates in the Actions Section**.** The proposed device does not raise new questions of safety or effectiveness as the predicate device and therefore substantially equivalent**.**

Conclusion:

Based on the intended use, fundamental scientific technology, technological characteristics and the intended use, the following subject device Coated Vicryl™ Plus Antibacterial (Polyglactin 910) Absorable Suture is considered to be substantially equivalent to the predicated device.

** Trademark*
IRGACARE®* MP (triclosan) “Registered Trademark of BASF Group”