December 21, 2020

Ethicon Inc.
Joice Pappan
Regulatory Affairs Manager
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K201996
Trade/Device Name: Monocryl Plus Antibacterial Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: December 11, 2020
Received: December 14, 2020

Dear Joice Pappan:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201996

Device Name

MONOCRYL™ Plus Antibacterial Poliglecaprone – 25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture

Indications for Use *(Describe)*

MONOCRYL™ Plus Antibacterial Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

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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ETHICON, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon, Inc., a *Johnson & Johnson* company
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USA

Contact Person: Joice Pappan
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Date Prepared: July 17, 2020

Device Trade Name: MONOCRYL™ Plus Antibacterial Poliglecaprone – 25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture

Device Common Name: Suture, Absorbable, Synthetic, Polyglycolic Acid

Class: II

Classification Name: Absorbable poly(glycolide/l-lactide) surgical suture (21 CFR878.4493)

Product Code: GAM

Predicate Device:

Predicate Device	510(k) Number
MONOCRYL™ Plus Antibacterial Poliglecaprone – 25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture	K050845

Device Description:

MONOCRYL™ Plus Antibacterial Suture is a sterile, monofilament, synthetic, absorbable surgical suture composed of a copolymer of glycolide and (epsilon) ε-caprolactone. The empirical formula of the polymer is $(C_2H_2O_2)_m$ $(C_6H_{10}O_2)_n$.

MONOCRYL™ Plus Antibacterial Suture is available undyed and dyed with D&C Violet No. 2

MONOCRYL™ Plus Antibacterial Suture contains Irgacare®‡ MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 µg/m.

Indications for Use:

MONOCRYL™ Plus Antibacterial Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Summary of Technological Characteristics and Performance:

The modified MONOCRYL™ Plus Suture has the same technological characteristics as the predicate device. Like the currently marketed predicate device, it is a sterile, monofilament synthetic absorbable suture that complies with the requirements of the United States Pharmacopoeia (USP) for absorbable surgical sutures except for a slight oversize in diameter.

Like the current marketed MONOCRYL™ Plus Antibacterial Suture, the modified device will continue to be available as a suture product with Irgacare®‡ MP, an antibacterial agent.

In vitro efficacy studies were conducted to demonstrate that bacteria will not colonize MONOCRYL™ Plus Antibacterial suture. The in vitro data indicated that MONOCRYL™ Plus suture provides an antibacterial effect sufficient to inhibit colonization of the suture by *Staphylococcus aureus, Staphylococcus epidermidis, Methicillin-Resistant S. aureus, Methicillin-Resistant S. epidermidis, Klebsiella pneumoniae, Escherichia coli* and *Enterobacter cloacae.*

Substantial Equivalence:

The modified device has the same intended use and indications for use as the predicate device. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed device. The modified device and currently marketed device differ only in the labeling (Instruction for Use and device box) which have been revised for updating in-vitro effectiveness against an additional microorganism and to include new descriptor and icon to allow customers to easily distinguish between Ethicon MONOCRYL™ suture and Ethicon MONOCRYL™ Plus suture.

Conclusion:

Since there will be no physical or technological characteristic changes to the currently marketed predicate device, the proposed labeling changes has shown to be appropriate for its intended use. Therefore, the modified device is substantially equivalent to the predicate device.

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