



June 25, 2026

Ethicon, Inc.  
Ryan Brown  
Senior Regulatory Affairs Program Lead  
1000 Route 202 South  
Raritan, New Jersey 08869

Re: K253394

Trade/Device Name: Coated VICRYL™ (Polyglactin 910) 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: May 22, 2026

Received: May 22, 2026

Dear Ryan Brown:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**TEK N. LAMICHHANE**  
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Tek N. Lamichhane, Ph.D.  
Assistant Director  
DHT4B: Division of Plastic and  
Reconstructive Surgery Devices  
OHT4: Office of Surgical and  
Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253394

?

Please provide the device trade name(s).

?

Coated VICRYL™ (Polyglactin 910) Plus Antibacterial Suture

Please provide your Indications for Use below.

?

Coated VICRYL™ Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Ethicon, Inc.
Applicant Address	1000 Route 202 South Raritan NJ 08869 United States
Applicant Contact Telephone	1 908-927-4719
Applicant Contact	Mr. Ryan Brown
Applicant Contact Email	rbrown53@its.jnj.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Coated VICRYL™ (Polyglactin 910) Plus Antibacterial Suture
Common Name	VICRYL™ Plus
Classification Name	GAM (Class 2) – Suture, Absorbable, Synthetic, Polyglycolic Acid: 878.4493 – Absorbable poly(glycolide/l-lactide) surgical suture
Regulation Number	878.4493
Product Code(s)	GAM

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181652	Coated VICRYL™ (Polyglactin 910) Plus Antibacterial Suture	GAM

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

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 triclosan, a broad spectrum antibacterial agent, at no more than 472 µg/m.

For Triclosan Drug Master File for the subject device, please reference BASF DMF 012097.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Coated VICRYL™ Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same between the subject device and the predicate device.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

There are no technical differences between the subject device and the predicate device. They are physically identical, this submission only concerns non-indication-for-use changes to the Instructions for Use of the subject device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

This submission relies upon publicly available, independently published randomized controlled trials and meta-analyses studying the relationship between Ethicon's Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Absorbable Suture and surgical site infection.

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