October 03, 2025

Internacional Farmacéutica S.A de C.V
Diana Berriozabal
Regulatory Intelligence Manager
Circuito De La Industria Poniente Lote 10-c Colonia Parque
Industrial El Cerrillo
Lerma, 52000
Mexico

Re: K252820
Trade/Device Name: PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures (Calypso); PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures (Odysseus)
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 4, 2025
Received: September 4, 2025

Dear Diana Berriozabal:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TEK N. LAMICHHANE -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252820

Device Name

Atramat® PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures

Indications for Use *(Describe)*

Atramat® PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K252820

1. **Submitter's Identification:**

   IINTERNACIONAL FARMACEUTICA, S.A. DE C.V.

   CIRCUITO DE LA INDUSTRIA PONIENTE LOTE 10-C COLONIA PARQUE INDUSTRIAL EL CERRILLO LERMA, Mexico, 52000

2. **Submission Correspondent**

   DIANA BERRIOZABAL
   Regulatory Intelligence Manager
   Phone: +525511050260
   E-mail: diana.berriozabal@atramat.com

3. **Date Prepared**

   Sep. 4th, 2025

4. **Device Identification:**

Trade/Proprietary Name:	Atramat® PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures
Common/Usual Name:	Poly(glycolide-co-L-lactide) Surgical Sutures
Classification Name:	Poly(glycolide-co-L-lactide) Surgical Sutures
Review Panel	General & Plastic Surgery Devices Panel
Regulation Number:	878.4493
Class:	Class II
Product Code:	GAM

5. **Device Description**

   The subject devices, ATRAMAT® PGLA90 (Calypso/Odysseus), are modifications to the previously cleared Atramat® PGLA90 Poly(glycolide-co-L-lactide) Surgical Suture (K072859). The predicate device is a synthetic, absorbable, sterile surgical suture composed of a copolymer of glycolide and L-lactide, which is indicated for soft tissue approximation.

ATRAMAT® PGLA90 (Calypso/Odysseus) devices integrate the predicate suture into a metal part with a pre-tied knot mechanism. This modification changes the operating method from traditional hand-tying to a pre-tied knot closure.

6. Indication for use:

Atramat® PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.

7. Technological Characteristics Comparison to Predicate Device

The subject devices, ATRAMAT® PGLA90 (Calypso/Odysseus), are claimed to be substantially equivalent to the Atramat® PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures, which were cleared under 510(k) K072859. The fundamental technology, intended use, and suture material are identical to the predicate device.

Comparison of Characteristics

	Subject Product K252820		**Predicate Product K072859**	**Comments**	**Comparison**
	ATRAMAT®PGLA90 (Calypso) 	**ATRAMAT®PGLA90 (Odysseus)** 	**Atramat®PGLA90** 		
Product Code / Regulation	GAM/ 21 CFR 878.4493	GAM/ 21 CFR 878.4493	GAM/ 21 CFR 878.4493		Same
Intended Use	Absorbable surgical sutures for use in soft tissue	Absorbable surgical sutures for use in soft tissue	Absorbable surgical sutures for use in soft tissue		Same
Indications for Use	General soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not	General soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not	General soft tissue approximation and/or ligation, including use in ophthalmic procedures, but		Same

	for use in cardiovascular and neurological tissues.	for use in cardiovascular and neurological tissues.	not for use in cardiovascular and neurological tissues.		
Material	PGLA	PGLA	PGLA		Same
Suture Characteristics	Synthetic absorbable multifilament	Synthetic absorbable multifilament	Synthetic absorbable multifilament		Same
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide		Same
Size (USP)	Compliant with USP 2 to 6-0	Compliant with USP 2 to 6-0	Compliant with USP 2 to 6-0		Same
Suture Contact Type	Implant, Absorbable	Implant, Absorbable	Implant, Absorbable		Same
Suture Contact Duration	56 - 70 days	56 - 70 days	56 - 70 days		Same
Dimensions L*W*H(mm)	Metal part 10*4*2.4	Metal part 13*5*1.8	Without metal part	The subject product with one metal part at the end of suture.	Different
Suture Tensile Strength	Compliant with USP <881> requirements	Compliant with USP <881> requirements	Compliant with USP <881> requirements		Same
Suture-Needle Attachment	Compliant with USP <871> requirements	Without Needle	Compliant with USP <871> requirements		Same
Accessories	Metal part	Metal part	Without metal part	The subject product with one metal part at the end of suture.	Different

Accessory Material (Patient Contacting)	Stainless Steel (SUS 302	Stainless Steel (SUS 302	Stainless Steel (SUS 302		Same
Operating Method	Utilizes a pre-tied knot to simplify knotting process	Utilizes a pre-tied knot to simplify knotting process	Hand-tying knotting process	The subject devices simplify the knotting process by using a pre-tied knot, whereas the predicate device requires a manual, hand-tying process.	Different
Mechanism	Double sheet band of single loop	Double sheet band of double loop	Surgeon Knot	The subject devices are with a pre-tied knot on a metal part.	Different

This submission is to add the following to the products cleared under K072859:

- Dimensions L*W*H(mm)
- Accessories
- Operating Method
- Mechanism

8. Non-Clinical Performance Data

Additional non-clinical testing was conducted for this 510(k) submission in accordance with the FDA guidance "Class II Special Controls Guidance Document: Surgical Sutures" to confirm that the subject devices meet all design inputs and specifications.

The technological differences between the subject devices and the predicate relate to the product's final dimensions, accessories, operating method, and mechanism. These differences all stem from a single design innovation: the subject devices incorporate a metal part with a pre-tied knot, which is designed to simplify the

surgical procedure by removing the need for manual, hand-tied knots.

Performance testing was conducted to ensure that these modifications do not introduce new concerns regarding safety or effectiveness. To validate the integrity of the new pre-tied knot mechanism, knot-pull tensile strength was evaluated per the USP <881> standard. The biocompatibility evaluation of additionally introduced components were assessed.

The results of this non-clinical performance testing demonstrate that the subject devices are substantially equivalent to the predicate device.

No animal testing was conducted for this submission

No clinical testing was conducted for this submission

9. Statement of Substantial Equivalence

Based on all testing and evidence, the subject device presents no new concerns regarding safety or effectiveness. For its intended use and indications for use, its performance is at least as safe and effective as the predicate device. Therefore, the device is considered substantially equivalent to the predicate.