



September 29, 2026

Riverpoint Medical, LLC
Rose Nakaweesi
Regulatory Affairs Associate II
825 NE 25th Ave.
Portland, Oregon 97232

Re: K263073

Trade/Device Name: Fast Absorbing PGLA
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 1, 2026
Received: September 1, 2026

Dear Rose Nakaweesi:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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) 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

Indications for Use

510(k) Number (if known)

K263073

Device Name

Fast Absorbing PGLA

Indications for Use (Describe)

Fast absorbing PGLA suture is indicated for use in superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular or neurological procedures. Fast Absorbing PGLA suture is provided sterile as a single use device

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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510(K) SUMMARY
K263073
Fast Absorbing PGLA suture

Submitter Information

Submitter's Name: Riverpoint Medical, LLC
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Portland, OR 97232
Phone Number: (503) 517-8001 or 866 445-4923
Fax Number: (503) 517-8002
Registration Number: 3006981798
Contact Person: Rose Nakaweesi
(503) 517-8001
Date of Preparation: September 29th 2026

Device Name

Trade Name: Fast Absorbing PGLA
Common or Usual Names: Absorbable Surgical sutures: PGLA
Classification Name: General and Plastic Surgery Devices

Device Classification

Device Class: II
Regulation Number: 878.4493: suture, absorbable, synthetic, polyglycolic acid
Product Code: GAM
Review Panel: General & Plastic Surgery
Premarket Review: Office of Surgical and Infection Control Devices (OHT4)
Plastic and Reconstructive Surgery Devices (DHT4B)

Predicate Device

K120556: Fast Absorbing PGLA: Vilet Quick
Device Class: II
Regulation Number: 878.4493: suture, absorbable, synthetic, polyglycolic acid
Product Code: GAM
Review Panel: General & Plastic Surgery
Premarket Review: Office of Surgical and Infection Control Devices (OHT4)
Plastic and Reconstructive Surgery Devices (DHT4B)

Device Description

Fast Absorbing PGLA sutures are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. Fast Absorbing PGLA sutures are multifilament and are composed of braided strands of Polyglycolic-Lactic Acid (PGLA) coated with Poly(glycolide-co-L-lactide) and Calcium Stearate attached to a standard medical grade suture needle, as applicable (sutures can be provided without needles as well). Available Suture sizes will be standard according to USP 32 requirements (8/0 through 3, depending on suture type).

Intended Use / Indications for Use

Fast absorbing PGLA suture is indicated for use in superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7-10 days) is required, **but not for use in ligation, ophthalmic, cardiovascular or neurological procedures**. Fast absorbing PGLA suture is provided sterile as a single use device.

Substantial Equivalence and Comparison of Technical Characteristics

The Fast absorbing PGLA sutures within this submission have substantially equivalent technological characteristics as the predicate device listed. As with the predicate device, Fast absorbing PGLA sutures are braided, coated, synthetic absorbable surgical sutures. The Fast absorbing PGLA sutures absorbable sutures are provided sterile for one-time use only and meet USP requirements unless stated otherwise within labeling. The only difference from the predicate device is the updated labeling related to the addition of a contraindication where the subject device is not for use in ligation, ophthalmic, cardiovascular, or neurological procedures

Performance Data

Fast absorbing PGLA sutures per FDA's *Special Control Guidance Document: Surgical Sutures*, performance testing, including mechanical testing in accordance with USP for synthetic absorbable suture, biocompatibility testing in accordance with ISO 10993-1, and *in-vitro* as well as *in-vivo* resorption testing has been performed to ensure substantial equivalence with the predicate device listed. All testing performed has demonstrated that Fast absorbing PGLA sutures meet current performance requirements for synthetic absorbable braided surgical sutures, and that they are substantially equivalent to the applicable predicate device.

Conclusion

Based on the information provided within this Special 510(k) submission, Riverpoint Medical concludes that the proposed suture products are substantially equivalent to the predicate device listed (K120556 Fast Absorbing PGLA: Vilet Quick).