October 16, 2025

Riverpoint Medical
Bianca Silva De Sousa
Regulatory Associate II
825 NE 25th Ave
Portland, Oregon 97232

Re: K253024
Trade/Device Name: ProZip Knotless Implant
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: September 19, 2025
Received: September 19, 2025

Dear Bianca Silva De Sousa:

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.

510(k) Number *(if known)*
K253024

Device Name
ProZip Knotless Implant

Indications for Use *(Describe)*
The ProZip Knotless Implant is intended for use in soft-tissue approximation.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K253024

ProZip Knotless Implant

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Bianca Silva de Sousa (503) 517-8001
Date of Preparation:	September 19, 2025

Device Name

Trade Name:	ProZip Knotless Implant
Common or Usual Names:	Polyblend Suture, Non-absorbable Surgical Sutures
Classification Name:	Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture

Device Classification

FDA Class:	II
Product Classification:	878.5000: Suture, nonabsorbable, synthetic, polyethylene
Classification Code:	GAT
Review Panel:	General & Plastic Surgery
Premarket Review	Office of Device Evaluation Division of Surgical Devices, Plastic and Reconstructive General Surgery Devices Branch

Predicate Device

K190817 – Riverpoint Medical HS Fiber

No reference devices were used in this submission.

Device Description

The ProZip Knotless Implant is comprised of braided ultra-high molecular weight polyethylene (UHMWPE) and Polyester sutures. It contains one working suture, also referred to as the repair strand, and shuttle strand that is used to shuttle the repair strand around the tissue. Additionally, the repair strand has a suture attached at either end to aid in passing through tissue, known as adaptor tail.

Sutures supplied meet United States Pharmacopeia (USP) requirements for non-absorbable suture except for diameter. Suture dyes are FDA approved. The device is sterilized by ethylene oxide gas and is provided sterile for single use. The device is intended for use in a hospital/clinic/surgical setting.

Intended Use and Indications for Use

The ProZip Knotless Implant is intended for use in soft-tissue approximation.

Substantial Equivalence and Comparison of Technical Characteristics

ProZip Knotless Implant is substantially equivalent to the previously cleared HS Fiber per K190817 "predicate device." ProZip Knotless Implant and the predicate device have the same intended use and indications for use, are manufactured from the same materials, are packaged using the same packaging materials, and are sterilized using the same validated methods.

The subject device differs from the predicate device with respect to:

(i) Technological characteristics: The subject device is composed of a repair strand, shuttle strand, adaptor tail, while the predicate device is composed of a repair strand only.

(ii) Principles of operation: the subject device includes a shuttle strand and an adaptor tail that enable soft tissue approximation without the need for knot tying. The predicate device does not include these features and instead relies on conventional knot tying techniques.

A summary of the technical characteristics' comparison can be found in the table below:

	ProZip Knotless Implant Subject Device	**HS Fiber** Predicate Device	**Evaluation**
Device Description	The ProZip Knotless Implant is comprised of braided ultra-high molecular weight polyethylene (UHMWPE) and Polyester sutures. It contains one working suture, also referred to as the repair strand, and shuttle strand that is used to shuttle the repair strand around the tissue. Additionally, the repair strand has a suture attached at either end to aid in passing through tissue, known as adaptor tail.	The Riverpoint Medical HS Fiber® sutures are non-absorbable, sterile, surgical sutures composed of multiple single strands of ultra-high molecular weight polyethylene (UHMWPE) braided together to form the implant. HS Fiber sutures are available in common sizes and lengths with or without pre-attached needles.	Similar description.
Intended Use/Indications	The ProZip Knotless Implant is intended for use in soft-tissue	HS Fiber sutures are indicated for use in general soft tissue	Same intended use.

	ProZip Knotless Implant Subject Device	**HS Fiber** Predicate Device	**Evaluation**
for Use	approximation.	approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues for orthopedic procedures.	
Principle of Operation	Pass Suture, Position Tails, Shuttle the Repair, Tension and Complete Repair	Pass Suture, Tension and Complete Repair	Similar principles of operation.
Materials	UHMWPE, Polyester	UHMWPE, Polyester	Same materials.
Regulation Number	878.5000	878.5000	Same regulation number.
Regulatory Class	II	II	Same regulatory class.
Prescription or OTC	Prescription	Prescription	Same access.
Product Code	GAT	GAT	Same product code.
Packaging	Tyvek/Poly Pouch	Tyvek/Poly Pouch	Same packaging.
Sterilization	EtO Sterilization	EtO Sterilization	Same sterilization method.

These differences are within the range of currently marketed devices, and they have been assessed through risk analysis, not raising any new questions of safety of effectiveness. Therefore, the ProZip Knotless Implant "subject device" is substantially equivalent to the "predicate device" and does not raise any issues of safety or effectiveness.

Performance Data

The sutures used to construct the ProZip Knotless Implants meet requirements established by the United States Pharmacopeia (USP), except for diameter. The UHMWPE sutures are tested per USP performance requirements for tensile strength.

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Non-clinical performance testing for the ProZip Knotless Implant included shelf-life testing, sterilization adoption validation, biocompatibility testing per ISO10993- 1:2018 - *Biological Evaluation of Medical Devices*, stability testing on the product packaging per ISO 11607-1:2006 - *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*, usability engineering validation with simulated use in a cadaveric models performed per EN62366: 2015- *Medical devices - Application of usability engineering to medical devices.*

Non-clinical mechanical testing was performed to verify the fixation strength of the ProZip

Knotless Implant using cyclic and ultimate tensile strength testing as compared to the predicate device. Results of performance testing for the ProZip Knotless Implant device concluded that the device performed comparably to the predicate device and the validations performed demonstrated that the device met all requirements for its intended use.

Conclusion

The information provided in this Special 510(k) demonstrates that the ProZip Knotless Implant is substantially equivalent to the predicate device.