November 30, 2023

Riverpoint Medical
Becca DeFrancia
Regulatory Affairs Manager
825 NE 25th Avenue
Portland, Oregon 97232

Re: K233552
Trade/Device Name: IDEAL Ziploop
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 3, 2023
Received: November 3, 2023

Dear Becca DeFrancia:

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.

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,

Sara S. Thompson -S

For

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic 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)*

K233552

Device Name

IDEAL Ziploop

Indications for Use *(Describe)*

The Riverpoint Medical IDEAL Ziploop is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon reconstruction.

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
Riverpoint Medical IDEAL Ziploop Adjustable Button Loop

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or (971) 288-1083
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Becca DeFrancia (503) 517-8001
Date of Preparation:	November 3, 2023

Device Name

Trade Name:	IDEAL Ziploop
Common or Usual Names:	Suture Retention Device, Button Loop
Classification Name:	Fastener, Fixation, Non-Degradable, Soft Tissue

Device Classification

FDA Class:	II
Product Classification:	888.3040: Smooth or threaded metallic bone fixation fastener
Classification Code:	MBI

Predicate Device

K171060 – Riverpoint Medical OrthoButton AL

K230212 – Riverpoint Medical OrthoButton AL

Device Description

The Riverpoint Medical IDEAL Ziploop adjustable button loop is comprised of an ultra-high molecular weight polyethylene (UHMWPE) loop combined with or without a titanium (Ti-6Al-4V ELI per ASTM F136) plate or as a single titanium (Ti-6Al-4V ELI per ASTM F136) plate. Additional non-absorbable sutures consisting of UHMWPE looped through the titanium plate to aide in assembly of the device and passing the plate through the intended void. The UHMWPE is available undyed (white), dyed blue, or dyed black. A titanium (Ti-6Al-4V ELI per ASTM F136) plate or button is affixed to the loop during the procedure for configurations where the button is not pre-attached to the loop. For models that come with a pre-attached titanium plate, the procedure is the same except the titanium plate is passed through the void. In both configurations, additional sutures are used to pass the loop and titanium plate (if pre-attached) parallel through the bone tunnel and secure into place.

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.

The classification for the IDEAL Ziploop is FDA Class II device with product classification 21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener, Product Code MBI.

Intended Use / Indications for Use

The Riverpoint Medical IDEAL Ziploop is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon reconstruction.

Performance Data

The sutures used to construct the IDEAL Ziploop meet requirements established by the United States Pharmacopeia (USP), except for diameter. The UHMWPE sutures are tested per USP performance requirements for tensile strength. Non-clinical performance testing for the IDEAL Ziploop included a sterilization adoption validation, biocompatibility testing per ISO10993- 1:2018 - Biological Evaluation of Medical Devices, product packaging validation 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. LAL and rabbit pyrogencity testing has demonstrated that the IDEAL Ziploop does not raise any additional concerns regarding pyrogenicity. Non-clinical mechanical testing was performed to verify the fixation strength of the IDEAL Ziploop using cyclic testing as compared to the predicate device. Results of performance testing for the IDEAL Ziploop device concluded that the device performed comparably to the predicate device and the validations performed demonstrated that the IDEAL Ziploop met all requirements for its intended use.

Substantial Equivalence and Comparison of Technical Characteristics

The IDEAL Ziploop product line has the same intended use and indications for use, the same principles of operation, and similar technical characteristics as the predicate device. Both the IDEAL Ziploop and the predicate device are sterilized using the same processes, are composed of the same materials, and are tested per the same performance requirements. The minor difference in technical characteristics is limited to 1) a new button design, 2) affixing a clip-on button component for configurations without a pre-attached button, 3) new implantable suture loop configurations and 4) new packaging insert. These minor differences do not raise new questions of safety or effectiveness; therefore, the IDEAL Ziploop product line is substantially equivalent to the currently marketed OrthoButton AL predicate device.

Conclusion

The information provided in this Special 510(k) demonstrates that the Riverpoint Medical IDEAL Ziploop is substantially equivalent to the predicate device.