February 23, 2023

Riverpoint Medical, LLC
Rebecca DeFrancia
Regulatory Affairs Associate
815 NE 25th Ave
Portland, Oregon 97232

Re: K230212
Trade/Device Name: OrthoButton® AL
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 26, 2023
Received: January 26, 2023

Dear Rebecca 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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230212

Device Name
OrthoButton® AL

Indications for Use *(Describe)*
The Riverpoint Medical OrthoButton® AL 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 OrthoButton® AL with Expanded instructions for use

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:	Rebecca DeFrancia (503) 517-8001
Date of Preparation:	January 25, 2023

Device Name

Trade Name:	OrthoButton® AL
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
Review Panel	Orthopedic
Premarket Review	Office of Product Evaluation and Quality Office of Health Technologies 6 (OHT6)– Office of Orthopedic Devices Division of Restorative, Repair and Trauma Devices

Predicate Device

K171060 – Riverpoint Medical OrthoButton® AL

Reference Device

K100652 – Arthex ACL Tightrope

Device Description

The Riverpoint Medical OrthoButton® AL is comprised of a braided ultra-high molecular weight polyethylene ("UHMWPE") adjustable loop combine with a titanium (Ti-6Al-4V ELI per ASTM F136) plate. The device is provided sterile for single use. The device is intended for use in a hospital/clinic/surgical setting.

The classification for the OrthoButton® AL 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 OrthoButton® AL is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon reconstruction.

Performance Data

Non-clinical performance testing for the Riverpoint Medical OrthoButton® AL included sterilization validation ISO 14937:2009 Sterilization of health care products- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices including biocompatibility ISO 10993-7:2008 for Biological evaluation of medical devices-Part 7 Ethylene Oxide Sterilzation Residuals, biocompatibility testing per ISO10993-1:2009 - Biological Evaluation of Medical Devices, stability testing on the product and packaging per ISO 11607-1:2006 - Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems, and a simulated use Usability Validation performed per EN62366: 2008-Medical devices - Application of usability engineering to medical devices. All acceptance criteria were met, and the Riverpoint Medical OrthoButton® AL performed as intended. LAL and rabbit pyrogencity testing has demonstrated that the OrthoButton® AL does not raise any additional concerns regarding pyrogenicity.

Substantial Equivalence and Comparison of Technical Characteristics

The OrthoButton® AL with expanded instructions for use is substantially equivalent to the previously cleared OrthoButton® AL cleared per K171060 "predicate device." The OrthoButton® AL has the same intended use, the same principles of operation, and the same technological characteristics as the predicate device. Both the OrthoButton® AL and the predicate device are comprised of the same materials, packaged using the same packaging materials and sterilized using the same processes. The OrthoButton® AL subject device contains slight labeling differences from the OrthoButton® AL predicate device in the following way: the instructions for use clarification for double button tibial fixation. However, this labelling characteristic for double button tibial fixation configuration is within the range of currently marketed devices including "reference device" Arthrex ACL Tightrope cleared per K100652.

Therefore, the OrthoButton® AL “subject device” is substantially equivalent to the predicate device in both labelling and intended use and does not raise any issues of safety or effectiveness.

Conclusion

The information provided in this Special 510(k) demonstrates that the Riverpoint Medical OrthoButton® AL subject device with expanded instructions for use is substantially equivalent to the predicate device.