September 18, 2020

Riverpoint Medical
Amanda Cole
Regulatory Affairs Associate
825 NE 25th Avenue
Portland, Oregon 97232

Re: K202399
Trade/Device Name: OrthoButton FL™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 20, 2020
Received: August 21, 2020

Dear Ms. Cole:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202399

Device Name
OrthoButton FL™

Indications for Use *(Describe)*
The Riverpoint Medical OrthoButton FL™ 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.

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510(k) SUMMARY

Riverpoint Medical OrthoButton FL™ Line Extension

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:	Edwin Anderson (503) 517-8001
Date of Preparation:	

Device Name

Trade Name:	OrthoButton FL™
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
Classification Code:	MBI
Review Panel	Orthopedic
Premarket Review	Office of Device Evaluation Division of Orthopedic Devices (DOD) Joint and Fixation Devices Branch

Predicate Device

K171060 – Riverpoint Medical OrthoButton® AL

Device Description

The Riverpoint Medical OrthoButton FL™ is available in multiple configurations, see device specifications in **Attachment 1**. Configurations may be comprised of an ultra-high molecular weight polyethylene (UHMWPE) loop provided 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, nylon, polyester, or polypropylene are 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) or with trace filaments of black, blue, or green color suture.

For configurations that do not have a titanium plate preattached, the titanium plate component is affixed to the loop during the procedure. For models that come with a preattached titanium plate, the procedure is the same except the titanium plate is passed through the channel. In both configurations, additional sutures are used to pass the loop and titanium plate (if pre-attached) parallel through the femoral channel and secure into place. The UHMWPE is available undyed (white), dyed blue, dyed black or with trace filaments of black, blue, or green color suture. Available Suture sizes are standard according to USP and EP requirements (dependent on suture type). The OrthoButton FL™ device is provided sterile for single use.

Intended Use / Indications for Use

The Riverpoint Medical OrthoButton FL™ 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 FL™ included sterilization validation per EN ISO14937:2009 - *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*, biocompatibility testing per ISO10993-1:2018 - *Biological Evaluation of Medical Devices,* stability testing on the product and packaging per ISO 11607-1:2019 - 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: 2015- Medical devices - *Application of usability engineering to medical devices*. Entotoxin/pyrogenicity testing, performed per ANSI/AAMI ST72:2019, USP <161>, and USP <85>. All acceptance criteria were met, and the Riverpoint Medical OrthoButton FL performed as intended.

Substantial Equivalence and Comparison of Technical Characteristics

The OrthoButton FL™ has the same intended use and indications for use, the same principles of operation, and similar technical characteristics as the predicate device. Both the OrthoButton FL™ 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 the packaging which allows the user to assemble the device prior to the procedure and affixing a clip-on button component for configurations without a preattached button. These minor differences do not raise new questions of safety or effectiveness; therefore, the OrthoButton FL™ line extension 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 OrthoButton FL™ line extension is substantially equivalent to the predicate device.