DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2017

Riverpoint Medical
Mr. Nathan Cook
Director of Quality Assurance
825 NE 25th Avenue
Portland, Oregon 97232

Re: K171060
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: May 15, 2017
Received: May 15, 2017

Dear Mr. Cook:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S
for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K171060

Device Name: OrthoButton AL™

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.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Riverpoint Medical OrthoButton® 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:	Nathan Cook (503) 517-8001
Date of Preparation:	March 31, 2017

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

Predicate Device

K160655 – Riverpoint Medical OrthoButton CL

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.

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 per ISO11135-1:2007 - Sterilization of Health Care Products Ethylene Oxide Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for medical devices, 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 simulated use Usability Validation performed per EN62366: 2008- Medical devices - Application of usability engineering to medical devices. The Riverpoint Medical OrthoButton AL™ was also evaluated for strength and elongation during cyclic loading and ultimate load to failure conditions. All acceptance criteria were met, and the Riverpoint Medical OrthoButton AL™ performed as intended.

Substantial Equivalence and Comparison of Technical Characteristics

The OrthoButton AL™ line extension is as safe and effective as the previously cleared OrthoButton CL®. The OrthoButton AL™ 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 AL™ and the predicate device are sterilized using the same processes, are composed of the same material, and are tested per the same performance requirements. LAL and rabbit pyrogencity testing has demonstrated that the OrthoButton AL™ does not raise any additional concerns regarding pyrogenicity. The minor difference in technical characteristics is limited to the ability for adjustment of the loop length. This difference does not raise new questions of safety or effectiveness; therefore, the OrthoButton AL™ line extension is substantially equivalent to the currently marketed predicate device.

Conclusion

The information provided in this Special 510(k) demonstrates that the Riverpoint Medical OrthoButton AL™ line extension is substantially equivalent to the predicate device.