



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

Riverpoint Medical  
Mr. Edwin Anderson  
Director of Quality and Regulatory  
825 NE 25th Avenue  
Portland, Oregon 97232

June 3, 2016

Re: K160655

Trade/Device Name: OrthoButton CL<sup>®</sup>

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: MBI

Dated: March 4, 2016

Received: March 8, 2016

Dear Mr. Anderson:

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 Parts 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" (21CFR 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 yours,

**Mark N. Melkerson -S**

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): \_\_\_\_\_K160655\_\_\_\_\_

Device Name: OrthoButton CL<sup>®</sup>

Indications for Use:

The Riverpoint Medical OrthoButton CL<sup>®</sup> is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon reconstruction.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) SUMMARY****Riverpoint Medical's OrthoButton CL****Submitter Information**

Submitter's Name: Riverpoint Medical  
Address: 825 NE 25<sup>th</sup> Ave.  
Portland, OR 97232  
Phone Number: (503) 517-8001 or 866 445-4923  
Fax Number: (503) 517-8002  
Registration Number: 3006981798  
Contact Person: Edwin Anderson  
(503) 517-8001  
Date of Preparation: March 4<sup>th</sup>, 2016

**Device Name**

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

**Device Classification**

FDA Class: 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 1

**Predicate Devices**

K133757 – Parcus Medical LLC, GFS Mini.

**Device Description:**

The Riverpoint Medical OrthoButton CL is comprised of a braided ultra-high molecular weight polyethylene ("UHMWPE") continuous loop combined 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 CL is intended for use in the fixation of bone and soft tissue in orthopedic procedures requiring ligament or tendon reconstruction.

### **Technological Characteristics**

The Riverpoint Medical Orthobutton CL is provided sterile, sterilized via ethylene oxide, for single use. The device is available in 10mm-60mm loop length configurations.

### **Substantial Equivalence**

The Riverpoint Medical OrthoButton CL has been designed and manufactured to be substantially equivalent to the Parcus Medical GFS Mini (“predicate device”) for all aspects of safety and effectiveness. The Riverpoint Medical OrthoButton CL and predicate device have the same intended use and indications, principles of operation, and have similar technological characteristics. Furthermore, the Riverpoint Medical Orthobutton CL and the predicate device have the same materials of construction, button shape, packaging materials, and sterilization methods. In conclusion, the Riverpoint Medical OrthoButton CL is substantially equivalent to the Parcus Medical GFS Mini.

### **Performance Data**

Non-clinical performance testing for the Riverpoint Medical Orthobutton CL 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 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 CL performed as intended.

### **Conclusion**

Based on the information provided within this 510(k) submission, the proposed Orthobutton CL does not raise significant questions of safety or effectiveness and may be considered substantially equivalent to the predicate device.