July 19, 2024

Skeletal Dynamics Inc
Alexandra Rodriguez Rojas
Regulatory Affairs Manager
7300 North Kendall Drive
Suite 800
Miami, Florida 33156

Re: K240835
Trade/Device Name: Suture Button Repair System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 17, 2024
Received: June 17, 2024

Dear Alexandra Rodriguez Rojas:

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,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2024.07.19 14:06:58 -04'00'

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

510(k) SUMMARY
Skeletal Dynamic's
Suture Button Repair System

Submitter

Skeletal Dynamics, Inc.
7300 N. Kendall Drive, Suite 800
Miami, FL 33156
Phone : 305-596-7585
E-mail : arodriguez@skeletaldynamics.com
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: July 18, 2024

Name and Classification

Trade Name: Suture Button Repair System
Common Name: Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name: Smooth or threaded metallic bone fixation fastener
Classification Number: 21 CFR §888.3040
Regulatory Class: Class II
Product Code: MBI

Primary Predicate Device

Riverpoint OrthoButton AL (K171060)

Reference Devices

Hs Fiber (Polyblend), River Bond, Riversilk (Silk), Riverpro (Polypropylene), Riverlon (Nylon)
Model Varies by Size/Need (K100006)
Geminus Volar Distal Radius Plate System (K182492)
Headless Compression Screw System (K143624)
Mini Tightrope Ft Repair Kit (K071978)

Device Description

The Suture Button Repair System is comprised of the following Suture Button configurations in conjunction with accessories: (1) Distal Bicep Suture Button Repair configuration, (2) IOL Suture Button-Repair configuration and (3) CMC Suture Button Repair configuration. The implants are provided sterile for single use. The instruments are provided non-sterile and shall be sterilized by the end user.

Indications for Use

The Suture Button Repair System is intended for fixation of bone and soft tissue in upper extremity orthopedic procedures requiring ligament or tendon reconstruction in the hand, wrist, forearm, elbow and shoulder.

Performance Testing

Non-clinical performance testing for the Suture Button Repair System included sterilization validation per *ISO11135-1 - 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 - Biological Evaluation of Medical Devices*, stability testing on the product and packaging per *ISO 11607-1- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*. The Suture Button Repair System was also evaluated for strength and elongation during cyclic loading and ultimate load to failure conditions.

Substantial Equivalence and Comparison of Technical Characteristics

The Skeletal Dynamics Suture Button Repair System is as safe and effective as the previously cleared OrthoButton AL. The Skeletal Dynamics Suture Button Repair System has the same intended use, the same principles of operation, and similar technical characteristics as the predicate device. Both the Suture Button Repair System and the predicate device are sterilized using the same processes, are composed of the same materials, and are tested per the same performance requirements. Bench top performance testing demonstrated substantially equivalent mechanical performance as the predicate device. The minor difference in technical characteristics is limited to the Suture Button configurations. This difference does not raise new questions of safety or effectiveness; therefore, the Suture Button Repair System is substantially equivalent to the currently marketed predicate device.

Conclusions

The Skeletal Dynamic's Suture Button Repair System is substantially equivalent to the predicate device identified in this premarket notification.

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.

510(k) Number *(if known)*
K240835

Device Name
Suture Button Repair System

Indications for Use *(Describe)*
The Suture Button Repair System is intended for fixation of bone and soft tissue in upper extremity orthopedic procedures requiring ligament or tendon reconstruction in the hand, wrist, forearm, elbow and shoulder.

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.

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