Skeletal Dynamics, Inc.
Alexandra Rodriguez
Director of Regulatory Affairs
7300 N. Kendall Dr.
Suite 800
Miami, Florida 33156

Re: K261770
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: May 28, 2026
Received: May 29, 2026

Dear Alexandra Rodriguez:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Christopher Ferreira
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261770	?
Please provide the device trade name(s).		?
Suture Button Repair System		
Please provide your Indications for Use below.		?
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.		
Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

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

Submitter

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Contact Person: Alexandra Rodriguez Rojas
Date Prepared: July 29, 2026

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

Predicate Device

Suture Button Repair System (K240835)

Reference Devices

Hs Fiber (Polyblend), River Bond, Riversilk (Silk), Riverpro (Polypropylene), Riverlon (Nylon) Model Varies by Size/Need (K100006), Total Wrist Arthroplasty System (K243381)

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

The subject device has no changes to its technology, technological characteristics, or principles of operation compared with the predicate device; therefore, no additional bench performance testing was necessary to support substantial equivalence.

Substantial Equivalence and Comparison of Technical Characteristics

The Skeletal Dynamics Suture Button Repair System is as safe and effective as the previously cleared Suture Button Repair System. The Skeletal Dynamics Suture Button Repair System has the same intended use and indications for use, principles of operation, and technological characteristics as the predicate device. Both the Suture Button Repair System and the predicate device are sterilized using ethylene oxide gas, are composed of the same materials, and are tested per the same performance requirements. The change from single-lot sterilization to full production sterilization does not raise different questions of safety or effectiveness. Sterilization validation demonstrates that the subject Suture Button Repair System can be successfully sterilized to achieve the same sterility assurance level as the predicate device.

Conclusions

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