March 23, 2026

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

Re: K254288
Trade/Device Name: Clavicle Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 30, 2025
Received: December 31, 2025

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 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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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.	K254288

Please provide the device trade name(s).

Clavicle Fixation System

Please provide your Indications for Use below.

The Skeletal Dynamics Clavicle Fixation System is indicated for fractures, osteotomies, and non-unions of the Clavicle including osteopenic bone.

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)

K254288
510(k) SUMMARY
Skeletal Dynamic's
Clavicle Fixation System

Submitter

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E-mail: arodriguez@skeletaldynamics.com
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: December 30th, 2025

Name and Classification

Trade Name: Clavicle Fixation System
Common Name: Plate, Fixation, Bone.
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories.
Classification Number: 21 CFR §888.3030
Regulatory Class: Class II
Product Code: HRS

Predicate Devices

- A.L.P.S Clavicle Plating System (K173767)

Reference Devices

- Proximal Humerus Fixation System (K242436)
- Protean Fragment Plating System (K241815)
- Geminus Volar Plating System (K182492)

Device Description

The Clavicle Fixation System features titanium (Ti 6Al-4V ELI) bone plates, offered in various sizes for the repair of the superior midshaft and superior lateral regions, as well as the anterior midshaft and anterior lateral areas. Included in the Clavicle Fixation system are titanium (Ti 6Al-4V ELI) and Cobalt-Chrome (CoCrMo) bone screws offered in 2.5mm, 2.7mm and 3.5mm diameters. Each plate is designed to accept specific compatible screw sizes, depending on the plate configuration. In addition, the system offers pegs that accept orthogonal screws, K-wires, and specialized instrumentation. The system is provided non-sterile and is sterilized at the user's facility.

Indications for Use

The Clavicle Fixation System is intended for fractures, osteotomies, and non-unions of the Clavicle including osteopenic bone.

Substantial Equivalence
The Clavicle Fixation System is substantially equivalent to the A.L.P.S. Clavicle Plating System (K173767). Minor differences in the technological characteristics and indications for use do not present any concerns related to safety or effectiveness of the device.

Comparison of Technological Characteristics with the Predicate Device
The subject Clavicle Fixation System is substantially equivalent to the predicate A.L.P.S. Clavicle Plating System.

Differences between the subject device and the predicate device include variations in plate geometry and screw design. In addition, the subject device incorporates pegs used in conjunction with targeting guide instruments to facilitate orthogonal screw placement.

These technological differences do not raise new questions of safety or effectiveness, as demonstrated by mechanical performance testing and supportive justification showing that the subject device meets or exceeds the performance of the predicate device, and that screw performance testing is consistent with applicable FDA guidance.

Therefore, the subject device is substantially equivalent to the predicate device.

Performance Testing
Mechanical testing demonstrated that the Skeletal Dynamics Clavicle Fixation System is equivalent to the predicate devices currently marketed. Static and dynamic testing of the plates was conducted in accordance with ASTM F382-24, and screw testing, including driving torque, torsional yield strength, and axial pullout strength, was conducted in accordance with ASTM F543-23.

Additional non-standard testing was performed to evaluate the mechanical performance of the peg and screw interface. This test included torsional strength and axial pullout force assessments to characterize the pegs' ability to maintain fixation under rotational and axial loading conditions. Results demonstrated that the peg/screw construct provides mechanical performance consistent with the intended function of the system and does not represent a worst-case scenario relative to the overall construct.

Based on these results, the subject device performs as intended and is as safe and effective as the legally marketed predicate device.

Conclusions
The Skeletal Dynamics' Clavicle Fixation System is substantially equivalent to the predicate device identified in this premarket notification.