November 14, 2024

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

Re: K242436
Trade/Device Name: Proximal Humerus 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, HWC
Dated: August 16, 2024
Received: August 16, 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.

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 -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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Enclosure

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.

Submission Number *(if known)*

K242436

Device Name

Proximal Humerus Fixation System

Indications for Use *(Describe)*

The Proximal Humerus Fixtion System is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

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.

K242436
510(k) SUMMARY
Skeletal Dynamic's
Proximal Humerus Fixation System

Submitter

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E-mail : arodriguez@skeletaldynamics.com
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: November 08th, 2024

Name and Classification

Trade Name: Proximal Humerus Fixation System
Common Name: Plate, Fixation, Bone (Primary), Screw, Fixation, Bone.
Classification Name: Single/multiple component metallic bone fixation appliances and Accessories (Primary), Smooth or threaded metallic bone fixation fastener
Classification Number: 21 CFR §888.3030 (Primary), 21 CFR §888.3040
Regulatory Class: Class II
Product Code: HRS (Primary), HWC

Primary Predicate Device

- Biomet A.L.P.S Proximal Humerus Fixation System (ALPS PHP) (K143697)

Additional Predicate

- 4.0 mm screws of the Stryker AxSOS 3 Ti System (K181091)

Reference Devices

- Distal Humerus Plating System (K213895)

Device Description

The Skeletal Dynamics Proximal Humerus Fixation System is a set of medical-grade Titanium Alloy (Ti-6Al-4V ELI) bone plates and Titanium and Cobalt Chrome (CoCr) screws and pegs designed for the stabilization and repair of fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus in conjunction with general and specialized instrumentation. The implants and instruments are provided non-sterile and shall be sterilized at the health care facility.

Indications for Use

The Proximal Humerus Fixation System is indicated for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Substantial Equivalence

The Proximal Humerus Fixation System is substantially equivalent to the primary predicate A.L.P.S Proximal Humerus Fixation System (ALPS PHP), formerly referred to as Biomet Proximal Humerus Fixation System (K143697) and to the 4.0 mm screws of the additional

predicate Stryker AxSOS 3 Ti System (K181091). 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 Proximal Humerus Fixation System is substantially equivalent to the primary predicate Biomet A.L.P.S. Proximal Humerus Fixation System and to the 4.0 screws of the additional predicate Stryker AxSOS 3 Ti System (K181091).

Both predicate systems consist of the same types of components (bone plates and bone screws) as the subject device. Both predicate devices also provide suture holes within the head of the plates, like the subject proximal humerus plates. Both predicate devices offer 4.0 mm Cancellous Locking Screws. The primary predicate includes at least one curved plate configuration like the subject device and bending features on the plate. Finally, the primary predicate and the subject device offer additional options for the fixation of the greater tuberosity. The subject device offers accessory plates for this purpose, while the predicate device offers suture holes in their plate configurations.

The primary difference between the subject device and its predicate devices is the geometry of the plates and the screw designs. Additionally, the subject system includes accessory plates that aid in the fixation of the greater tuberosity when needed. The predicate device includes suture holes in their plates for the same purpose of fixation of the greater tuberosity when needed.

These differences in technology do not raise any new questions of safety or effectiveness due to the subject proximal humerus plates and screws performance testing results meeting the FDA guidance's that also cover the predicate devices.

Performance Testing
Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamics Proximal Humerus Fixation System is equivalent to predicate devices currently marketed. Static and Dynamic testing per ASTM F382-17 established equivalency for the plates. Driving Torque, Torsional Yield Strength, and Axial Pullout testing per ASTM 543-23 established equivalency for the screws. Therefore, the subject device is as safe and effective as the legally marketed predicate device.

Conclusions
The Skeletal Dynamics' Proximal Humerus Fixation System is substantially equivalent to the predicate devices identified in this premarket notification.