October 26, 2026

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

Re: K261135
Trade/Device Name: Trochlear Salvage Plating 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, OZI
Dated: September 23, 2026
Received: September 24, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 -S

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.	K261135

Please provide the device trade name(s).

Trochlear Salvage Plating System

Please provide your Indications for Use below.

The Trochlear Salvage System Plates are intended for the fixation of intra-articular distal humerus fractures, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus in skeletally mature patients. The IJS-E component is intended to provide temporary stabilization of the elbow joint following trauma or chronic elbow dislocation

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) #: K261135

510(k) Summary

Prepared on: 2026-10-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Skeletal Dynamics Inc
Applicant Address	7300 North Kendall Drive Miami fl 33156 United States
Applicant Contact Telephone	305-596-7585
Applicant Contact	Ms. Alexandra Rodriguez Rojas
Applicant Contact Email	arodriguez@skeletaldynamics.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Trochlear Salvage Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone / Internal Hinged Elbow Fixator
Regulation Number	888.3030
Product Code(s)	HRS, OZI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213895	Distal Humerus Plating System	HRS
K231447	Double Internal Joint Stabilizer- Elbow	OZI
K223318	Internal Joint Stabilizer- Elbow	OZI

Device Description Summary

21 CFR 807.92(a)(4)

The Skeletal Dynamics Trochlear Salvage Plating System includes distal humerus plates, referred to within this system as trochlear salvage plates , with PEEK bearing sleeves located in the most distal holes. These components are intended to interface with either the Double Internal Joint Stabilization (IJS) System (K231447), modified for use with a Ti6Al4V ELI Proximal Ulna Plate (K231623), or the IJS-E Base Plate Assembly, Proximal Ulna Plate (K223318).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Trochlear Salvage System Plates are intended for the fixation of intra-articular distal humerus fractures, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus in skeletally mature patients. The IJS-E component is intended to provide temporary stabilization of the elbow joint following trauma or chronic elbow dislocation

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Trochlear Salvage Plating System (TSS) is substantially equivalent to the Skeletal Dynamics Distal Humerus Plating System (K213895) and the previously cleared Internal Joint Stabilizer (IJS) Systems (K231447 and K223318).

The subject and predicate systems have the same intended use and similar indications for use. Specifically, the Trochlear Salvage System

Plates are intended for the fixation of intra-articular distal humerus fractures, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus in skeletally mature patients. The IJS-E component is intended to provide temporary stabilization of the elbow joint following trauma or chronic elbow dislocation.

The predicate Distal Humerus Plating System is indicated for intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus. The predicate Internal Joint- Stabilizer – Elbow is intended to provide temporary stabilization of the elbow joint after trauma or chronic elbow dislocation. Thus, since the subject Trochlear Salvage Plating System indications for use fall within the intended use of the predicate devices, the subject device satisfies the first criterion for finding substantial equivalence.

Technological Comparison

21 CFR 807.92(a)(6)

The Trochlear Salvage Plating System (TSS) is substantially equivalent to the Skeletal Dynamics Distal Humerus Plating System (K213895) and the previously cleared Internal Joint Stabilizer (IJS) Systems (K231447 and K223318).

The Trochlear Salvage Plating System has the same general intended use, similar indications for use, and comparable technological characteristics and principles of operation as the identified predicate devices.
Both predicate systems include the same type of components with similar designs (bone plates, screws, and IJS constructs) as the subject device. The primary difference between the subject device and its predicate devices is the inclusion of a PEEK bearing, which serves as an interface between the trochlear salvage plates and the trochlear salvage axis pins.

Any differences in technological characteristics or indications for use are minor and do not raise new questions of safety or effectiveness. Performance testing, including bench evaluations, demonstrates that the Trochlear Salvage Plating System performs in a manner that is as safe and effective as the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Fatigue and wear testing were conducted on the Skeletal Dynamics Trochlear Salvage System (TSS) to evaluate mechanical performance and characterize wear of the PEEK bearing components under clinically relevant conditions.
The TSS meets fatigue performance requirements and demonstrates acceptable wear behavior under clinically relevant conditions. The PEEK bearing components maintain mechanical and functional integrity, and the observed wear does not adversely impact the safety or effectiveness of the device for its intended use.
All screws included in the system were previously evaluated and cleared under K213895; therefore, additional testing for the screws was not required.