September 26, 2024

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

Re: K241815
Trade/Device Name: Protean Fragment 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, HWC
Dated: June 21, 2024
Received: June 24, 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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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

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)*

K241815

Device Name

Protean Fragment Plating System

Indications for Use *(Describe)*

The Skeletal Dynamics Protean Fragment Plating System is intended for stabilization and fixation in fresh fractures, revision procedures, joint fusion, and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, clavicle, scapula, finger, toe, and pelvis, particularly in osteopenic bone with the appropriate configuration of the device. The system is intended for use in adult and pediatric populations (children and adolescents).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary- K241815
Skeletal Dynamic's
Protean Fragment Plating System

Submitter:
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Miami, FL 33156
Phone: 305-596-7585
Contact Person: Alexandra Rodriguez Rojas
E-mail: arodriguez@skeletaldynamics.com
Date Prepared: September 25th, 2024

Name and Classification:
Trade Name: Protean Fragment Plating 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, HWC

Predicate Devices:
Primary Predicate:
Depuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm Plates and Screws) (K150099).
Additional Predicates:
- Synthes Cortical Screws (K112583)
- ANTHEM® Fracture System (K212433)
- Protean Fragment Plating System (K140372)

Device Description:
The Skeletal Dynamics Protean Fragment Plating 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 small bone fragments 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 Skeletal Dynamics Protean Fragment Plating System is intended for stabilization and fixation in fresh fractures, revision procedures, joint fusion, and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, clavicle, scapula, finger, toe, and pelvis, particularly in osteopenic bone with the appropriate configuration of the device. The system is intended for use in adult and pediatric populations (children and adolescents).

Substantial Equivalence and Comparison of Technical Characteristics

The Protean Fragment Plating System is substantially equivalent to the DePuy Synthes Variable Angle Locking Hand System (1.3mm and 2.0mm Plates and Screws) (K150099) and the Synthes Cortical Screws (K112583) with respect to the technological characteristics and indications for use, and substantially equivalent to the ANTHEM® Fracture System (K212433) with respect to the indications for use. Although there are differences in technological characteristics, these differences do not present any concern of safety or effectiveness compared with the predicate systems, as demonstrated in the bench testing results.

Performance Testing

Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamics Distal Elbow Plating 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 against the guidance "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway", established safety and effectiveness for the screws. Therefore, the subject device is as safe and effective as the legally marketed predicate device.

Conclusions

The Skeletal Dynamic's Protean Fragment Plating System is substantially equivalent to the predicate device identified in this premarket notification.