August 1, 2024

Skeletal Dynamics Inc
Alexandra Rodriguez Rojas
Regulatory Affairs Manager
7300 SW Kendall Dr
Miami, Florida 33156

Re: K242055
Trade/Device Name: Freefix Forearm 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
Dated: July 12, 2024
Received: July 15, 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.

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, MS, RAC
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)*

K242055

Device Name

Freefix Forearm Plating System

Indications for Use *(Describe)*

The FreeFix Forearm Plating System is indicated for the treatment of fractures, fusions, and osteotomies of the radius and ulna.

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.

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510(k) SUMMARY
Skeletal Dynamic's
FreeFix Forearm Plating System

Submitter:
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Phone: 305-596-7585
E-mail: arodriguez@skeletaldynamics.com
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: July 29th, 2024

Name and Classification
Trade Name: FreeFix Forearm 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

Predicate Devices
Skeletal Dynamics Forearm Plating System (K200538)

Reference Devices
Distal Elbow Plating System (K231623)

Device Description
The FreeFix Forearm Plating System is comprised of plates, screws and specific instrumentation. The implants and instruments are provided non-sterile and shall be sterilized at the health care facility.

Indications for Use
The FreeFix Forearm Plating System is indicated for the treatment of fractures, fusions, and osteotomies of the radius and ulna.

Substantial Equivalence and Comparison of Technical Characteristics

FreeFix Forearm Plating System is substantially equivalent to the Forearm Plating System (K200538) with respect to the technological characteristics and indications for use. The FreeFix Forearm Plating System has the same general intended use and indications for use, similar technological characteristics, and principles of operation as the previously cleared predicate device mentioned above. Even though there are minor differences in the technological characteristics, these do not address any concerns related to safety or effectiveness of the device.

Comparison of Technological Characteristics with the Predicate Device

The subject FreeFix Forearm Plating System is substantially equivalent to the predicate Forearm Plating System. Both systems are indicated for fractures, fusions, and osteotomies of the radius and ulna. Both systems consist of the same types of components, i.e. plates, screws and specialized instrumentation.

The primary difference is the addition of 2.7mm locking and compression screws and minor modification to the plates to interface with these new screws.

These differences do not raise different questions of safety and effectiveness as demonstrated by the performance testing results and supportive justification.

Performance Testing

Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamics FreeFix Forearm Plating System is equivalent to the predicate device currently marketed. Mechanical testing, which established equivalency, includes ASTM F543-23, Standard Specifications and Test Methods for Metallic Bone Screws. All acceptance criteria were met, and the FreeFix Forearm Plating System performed better than its predicate device.

Conclusions

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