Skeletal Dynamics, Inc.
Ana Escagedo
President
7300 N. Kendall Drive, Suite 400
Miami, Florida 33156

September 30, 2021

Re: K211439
Trade/Device Name: Small Bone Nailing System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY, HSB
Dated: September 3, 2021
Received: September 7, 2021

Dear Ana Escagedo:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Michael Owens
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2020
*See PRA Statement below*

510(k) Number *(if known)*

K211439

Device Name

Small Bone Nailing System

Indications for Use *(Describe)*

The Skeletal Dynamics Small Bone Nailing System is indicated for the fixation of extra-articular fractures of the long bones of the hand including the metacarpals and the proximal phalanges.

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 Dynamics Inc.'s**
**Small Bone Nailing System**

**Submitter**

Skeletal Dynamics, Inc.
7300 N. Kendall Drive
Suite 400
Miami, FL 33156
Phone: 305-596-7585
Facsimile: 305-596-7591
Contact Person: Ana M. Escagedo
Date Prepared: May 3, 2021

**Name and Classification**

| | |
|---|---|
| Name: | Small Bone Nailing System |
| Common Name: | Pin, Fixation, Smooth<br>Rod Fixation, Intramedullary and Accessories |
| Classification: | 21 CFR §888.3040 and §888.3020 |
| Classification Name: | Smooth or Threaded Metallic Bone Fixation Fastener<br>Intramedullary Fixation Rod |
| Regulatory Class: | Class II |
| Product Code: | HTY, HSB |

**Predicate Devices**
Small Bone Fixation System, K033406

**Device Description**
The Skeletal Dynamics Small Bone Nailing System consists of intramedullary nails and screws with diameters of 2.1mm, 3.0mm, 3.5mm, and 4.0mm, and lengths from 25mm to 70mm to address proximal phalanx and metacarpal fractures. The intramedullary nails and screws are made of medical grade titanium alloy. Cobalt Chrome 1.7mm Locking and 1.5mm transfixion screws are also provided in various lengths. Included in the system is specialized instrumentation. The System is provided non-sterile for sterilization in the user facility.

The Small Bone Nailing System is comprised of:

- Titanium alloy intramedullary nails and screws
- CoCr locking screws and transfixion screws
- Stainless steel K-wires (for provisional fixation; not for implantation)
- System specific instrumentation

**Indications for Use**
The Small Bone Nailing System is indicated for fixation of extra-articular fractures of the long bones of the hand including the metacarpals and the proximal phalanges.

**Summary of Technological Characteristics**
The substantial equivalence of the Small Bone Nailing System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging and does not present any new issues of safety or effectiveness.

Both the subject device and the predicate device are similar in that they offer fixation for extra

articular fractures of the long bones of the hand, including the metacarpals and proximal phalanx and include locking features for implant/bone rotational stability. Differences between the subject and devices do not affect the safety and effectiveness of the subject device. These differences include: Fixation by means of two locking compression screws (one distal, one proximal) with the subject device; the predicate fixation is by way of a bent tip and one proximal locking device. The use of locking compression screws at both the proximal and distal ends with the subject device provides rigid fixation of the implant within the medullary canal. There is also a material difference between the subject device (made of medical grade titanium alloy) and the predicate device (made of stainless steel), however, both devices have the comparable mechanical properties.

**Performance Testing**
Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamics Small Bone Nailing System is equivalent to predicate devices currently marketed. Static and dynamic testing which established equivalency included:

- ASTM F2193-20, *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System* and ASTM-F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws.*
- ASTM F1264, *Standard Specification and Test Methods for Intramedullary Fixation Devices.*

Therefore, the subject device is as safe and effective as the legally marketed predicate device.

**Conclusions**
The Skeletal Dynamics Small Bone Nailing System is substantially equivalent to the predicate device identified in this premarket notification.