April 28, 2023

Skeletal Dynamics, Inc.
Alexandra Rodriguez Rojas
Regulatory Affairs Manager
7300 North Kendall Drive
Suite 400
Miami, Florida 33156

Re: K230908
Trade/Device Name: Hand Trauma Threaded Nail System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 30, 2023
Received: March 31, 2023

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 (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230908

Device Name

Hand Trauma Threaded Nail System

Indications for Use *(Describe)*

The Hand Trauma Threaded Nail System is indicated for the fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized threaded nail.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) SUMMARY
Skeletal Dynamic's
Hand Trauma Threaded Nail System

Submitter

Skeletal Dynamics, Inc.
7300 N. Kendall Drive
Suite 400
Miami, FL 33156
Phone: 305-596-7585
Facsimile: 305-596-7591
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: March 30, 2023

Name and Classification

Trade Name: Hand Trauma Threaded Nail System
Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener
Classification Number: 21 CFR §888.3040
Regulatory Class: Class II
Product Code: HWC

Predicate Devices

Hand Trauma Screw System, K220723

Device Description

The Skeletal Dynamic's Hand Trauma Threaded Nail System consists of cannulated and non-cannulated threaded nails, with distal and proximal threads with a pitch differential between the threads which creates compression during threaded nail insertion. The threaded nails are self-tapping, available in multiple diameters and various lengths and made of titanium alloy.

- 2.0mm non-cannulated Hand Trauma Threaded nail:12mm–28mm in 2mm increments
- 2.0mm non-cannulated Hand Trauma Threaded Nails: 28mm - 48mm in 4mm increments.
- 3.0mm cannulated Hand Trauma Threaded Nails: 20mm - 70mm in 5mm increments.
- 3.5mm cannulated Hand Trauma Threaded Nails: 25mm - 70mm in 5mm increments.
- 4.0mm cannulated Hand Trauma Threaded Nails: 25mm - 70mm in 5mm increments.

The system is provided non-sterile and is sterilized in the user facility.

Indications for Use

The Hand Trauma Threaded Nail System is indicated for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized threaded nail.

Summary of Technological Characteristics

The subject Hand Trauma Threaded Nail System is adding smaller sizes for the 2.0mm non-cannulated and 3.0mm Cannulated Threaded Nails. These additional sizes do not present any new issues of safety or effectiveness as demonstrated by the Axial Pullout Strength testing presented in the performance testing section. The substantial equivalence of the Hand Trauma Threaded Nail System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging.

Performance Testing

The addition of the smaller sizes for the 2.0mm Non-Cannulated Threaded Nails and the 3.0mm Cannulated threaded Nails was verified through an Axial Pullout Strength as it is the only testing affected by this change. The subject testing followed the FDA Guidance “Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway.” The results demonstrated that the Skeletal Dynamics new Hand Trauma Threaded Nail Sizes are as safe and effective as the predicate device.

Conclusions

The substantial equivalence of the Skeletal Dynamic’s Hand Trauma Threaded Nail System to the predicate device is demonstrated by similarities in indications for use, design (fundamental scientific technology), performance and operational principles, and does not present any new issues of safety or effectiveness. Thus, the subject Hand Trauma Threaded Nail System is an equivalent device to the Hand Trauma Screw System (K220723).