May 12, 2022

Skeletal Dynamics, Inc.
Alexandra Rodriguez
Regulatory Affairs Specialist
7300 N Kendall Drive, Suite 400
Miami, Florida 33156

Re: K220723
Trade/Device Name: Hand Trauma Screw 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 11, 2022
Received: March 14, 2022

Dear Alexandra Rodriguez:

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, 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.

510(k) Number *(if known)*
K220723

Device Name
Hand Trauma Screw System

Indications for Use *(Describe)*
The Hand Trauma Screw System is indicated for the fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized screw.

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.

510(k) SUMMARY
Skeletal Dynamic's
Hand Trauma Screw 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
Date Prepared: March 14, 2022

Name and Classification

Trade Name: Hand Trauma Screw 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

Primary predicate device: REDUCT® Headless Compression Screw, K201662
Additional predicate device: Tyber Medical Trauma Screws, K133842

Device Description

The Skeletal Dynamic's Hand Trauma Screw System consists of titanium screws and specialized instrumentation.

- 2.0mm non-cannulated Hand Trauma Screws: 24mm - 48mm in 4mm increments.
- 3.0mm cannulated Hand Trauma Screws: 25mm - 70mm in 5mm increments.
- 3.5mm cannulated Hand Trauma Screws: 25mm - 70mm in 5mm increments.
- 4.0mm cannulated Hand Trauma Screws: 25mm - 70mm in 5mm increments.

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

Indications for Use

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

Summary of Technological Characteristics

The substantial equivalence of the Hand Trauma Screw System to the predicate devices 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.

Performance Testing

Engineering analysis and mechanical testing were conducted as recommended in the FDA guidance document, "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway," published in December 2020. Engineering analysis and mechanical testing demonstrated that the Skeletal Dynamic's Hand Trauma Screw System is substantially equivalent to predicate devices currently marketed. Mechanical testing which established equivalency included ASTM-F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws.* Therefore, the subject device is as safe and effective as the legally marketed predicate device.

Conclusions

The Skeletal Dynamic's Hand Trauma Screw System is substantially equivalent to the predicate devices identified in this premarket notification.