July 16, 20202

Skeletal Dynamics, Inc.
Diana Taylor
Senior Regulatory Affairs Specialist
7300 N. Kendall Drive, Suite 400
Miami, Florida 33156

Re: K201662
Trade/Device Name: REDUCT® Headless Compression 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: June 17, 2020
Received: June 19, 2020

Dear Diana Taylor:

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

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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K201662

Device Name

REDUCT® Headless Compression Screw System

Indications for Use *(Describe)*

The Skeletal Dynamics REDUCT® Headless Compression Screw System is intended for 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)*

X 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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"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."

510(k) SUMMARY

REDUCT® Headless Compression 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: Diana Taylor
Date: July 16, 2020

Name and Classification

Name:	REDUCT® Headless Compression Screw System
Common Name:	Screw, Fixation, Bone
Classification:	21 CFR §888.3040
Regulatory Class:	Class II
Product Code(s):	HWC

Predicate Device: K143624, 1/13/2015 Skeletal Dynamics Headless Compression Screw System

Device Description
The REDUCT® Headless Compression Screw (HCS) System consists of the following screws from medical grade Titanium Alloy (ASTM F136).

- 2.5mm cannulated HCS screws: 10mm - 30mm
- 3.5mm cannulated HCS screws: 10mm - 50mm
- 4.5mm cannulated HCS screws: 20mm - 65mm
- 2.0mm non-cannulated HCS Arthrodesis screws: 20mm - 34mm
- 2.5mm cannulated HCS Arthrodesis screws: 26mm - 40mm
- 3.5mm cannulated HCS Arthrodesis screws: 32mm - 46mm

The REDUCT® Headless Compression Screw includes appropriate instrumentation, as identified in the surgical technique.

Indications for Use
The Skeletal Dynamics REDUCT® Headless Compression Screw System is intended 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 modified and predicate HCS Screws is demonstrated by similarities in intended use, indications for use, same materials, sterility and packaging, similar thread design, diameters and lengths. The differences include new smaller and larger diameter screws and additional lengths in existing diameters, and HCS Screws specific for the use in Arthrodesis.

Performance Testing
For confirmation of substantial equivalence, performance testing was completed in accordance with ASTM F543, *Standard Specification and Test Method for Metallic Medical Bone Screws,* including self-tap force, insertion torque testing, removal torque testing, torsional strength testing and pullout strength testing. Additionally bending strength and fatigue bending strength was completed in accordance to ASTM F2193, *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*. This testing demonstrates the modified HCS Screws are substantially equivalent to the predicate devices and present no new issues of safety or effectiveness compared to the predicate device.

Conclusions
The subject REDUCT® Headless Compression Screws are equivalent to the legally marketed predicate and present no new issues of safety or effectiveness.