September 15, 2023

Trax Surgical
Stephen Deane
Senior Vice President
75 Mill Street
Stoughton, Massachusetts 02072

Re: K230946
Trade/Device Name: Accelerate 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, HTN
Dated: August 9, 2023
Received: August 11, 2023

Dear Stephen Deane:

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.

510(k) Number *(if known)*
K230946

Device Name
Accelerate Compression Screw System

Indications for Use *(Describe)*
The Accelerate Compression Screw System is indicated for use in adult and skeletally mature pediatric patients (aged 12-21 years), for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

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."

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Accelerate Compression Screw System.

Submitted by:	Trax Surgical, Inc. 75 Mill Street Stoughton, MA 02072
Date:	March 13, 2023
Contact Person:	Stephen Deane 781.828.4400 sdeane@primomedicalgroup.com
Proprietary Name:	Accelerate Compression Screw System
Common Name:	Screw, Fixation, Bone Washer, Bolt, Nut
Classification Name and Reference:	21 CFR 888.3040 (Primary), Smooth or threaded metallic bone fixation fastener (Primary), Class II 21 CFR 888.3030, Single / multiple component metallic bone fixation appliances and accessories, Class II
Device Product Code, Device Panel:	HWC (Primary), HTN, Orthopedic
Primary Predicate Device:	Captivate Compression Screws (K222409)
Additional Predicate Devices:	GEO Bone Screw System (K202817) Treace Medical Concepts Snap-off Screw System (K183363)
Reference Device:	Arthrosurface Bone Screws (K172383)

5.1 Device Description

The Trax Accelerate Compression Screw System is intended to be used to treat fracture and reconstruction of the small bones of the extremities (hands and feet). The screws are manufactured from 6AL-4V titanium and are anodized in various colors for easy size recognition. Washers will be provided for some screw sizes as appropriate. The fixation screws come in three (3) different configurations, headed, headless and break away. The headed and headless screws are cannulated. The breakaway screws are solid. They vary in diameter and length to allow the surgeon to select the appropriate device for the patient's anatomy. All devices are intended to be provided in an autoclavable instrument tray that includes a set of Class I instruments. The set will be provided non-sterile to the end user.

The surgical instruments are intended to prepare the site and fixate the screws. The screws and instruments shall be designed to be maintained in an autoclavable tray. Replacement implants and instruments will be available separately as required.

5.2 Indication for Use

The Accelerate Compression Screw System is indicated for use in adult and skeletally mature pediatric patients (aged 12-21 years), for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

5.3 Performance Data

Performance of the Accelerate Compression Screw System was evaluated in accordance with ASTM F543-17 and the FDA guidance *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*. Static torsion (torque to failure), Insertion / Removal torque and Axial pullout testing was performed to demonstrate substantial equivalence to the predicate devices.

Biocompatibility of patient contacting materials was demonstrated by using materials that meet applicable standards and / or used in 510(k) cleared devices (K172383).

5.4 Technological Characteristics

The subject Accelerate Compression implants (screws and washers) have similar technological characteristics as the predicate devices including indications for use, materials and coatings, function and range of sizes.

Trax Surgical believes that the Accelerate Compression Screw System is as safe and effective and performs in a substantially equivalent manner to the predicate devices.

5.5 Conclusion

The subject Trax Surgical Accelerate Compression Screw System has been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance and intended use. The information provided supports substantial equivalence to the predicate device.