OsteoMed LLC
Andrew Johnson
Senior Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

October 15, 2020

Re: K202680
Trade/Device Name: OsteoMed ExtremiFix Mini & Small Cannulated 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: September 11, 2020
Received: September 15, 2020

Dear Andrew Johnson:

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)*
K202680

Device Name
OsteoMed ExtremiFix Mini & Small Cannulated Screw System

Indications for Use *(Describe)*
The Osteomed ExtremiFix Mini & Small Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

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

I. SUBMITTER

OsteoMed
3885 Arapaho Rd.
Addison, TX 75001 USA

Phone: 972-677-4795
Fax: 972-677-4601
Email: djohnson@osteomed.com

Contact Person: Drew Johnson
Date Prepared: September 11, 2020

II. DEVICE

Name of the Device:	OsteoMed ExtremiFix Mini & Small Cannulated Screw System
Common or Usual Name:	Bone Screw
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation:	888.3040
Regulatory Class:	II
Product Code:	HWC, HTN

III. PREDICATE AND REFERENCE DEVICES

Predicate Device: OsteoMed Headless Cannulated Screw System, K063298
Classification Name: Smooth or threaded metallic fixation fastener (21 CFR 888.3040, Product Code HWC)
Device Class: II

Reference Device: OsteoMed Cannulated Screw System, K151021
Classification Name: Smooth or threaded metallic fixation fastener (21 CFR 888.3040, Product Code HWC)
Device Class: II

Reference Device: OsteoMed ExtremiFix Mid & Large Screw System, K163303
Classification Name: Smooth or threaded metallic fixation fastener (21 CFR 888.3040, Product Code HWC, HTN)
Device Class: II

IV. DEVICE DESCRIPTION

The OsteoMed Mini & Small Cannulated Screw System is comprised of screws and washers used for bone fixation of the hand and foot following trauma or osteotomy. The System features cannulated screws in the following dimensions:

2.0mm screw diameter – 6 mm to 42 mm screw length;
2.4mm screw diameter – 6 mm to 50 mm screw length;
3.0mm screw diameter – 10 mm to 40 mm screw length;
4.0mm screw diameter – 12 mm to 52 mm screw length;

The system instruments include depth gauges, screwdrivers, countersinks, guide wires, and other instruments to facilitate the placement of screws.

The implants (screws and washers) of the OsteoMed ExtremiFix Mini & Small Cannulated Screw System are made from titanium alloy (ASTM F136). Modifications to the screws include changing the screw drive connection from a trilobe to a hexalobe and adding a headed screw option for each of the screw size offerings (2.0, 2.4, 3.0, and 4.0 mm diameters). The screws and washers are intended for single use only.

The subject device's system instruments include k-wires, drills, countersinks, drivers, tissue protectors, and screw extractor. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymer. The k-wires, screw extractor, and drills are intended for single use only.

V. INDICATIONS FOR USE

The OsteoMed ExtremiFix Mini & Small Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject device, OsteoMed ExtremiFix Mini & Small Cannulated Screw System, and the predicate device use the same fundamental technology. Both achieve this through same diameters and lengths for screw size offerings and is recommended for fracture fixation of bones appropriate for the size of the device. The subject device will now have an option of headed screws, which have the similar dimensions and screw thread as the predicate devices. The subject device will also have a hexalobe driver interface compared to the primary predicate trilobed screw interface design; however, it is a similar driver interface compared to OsteoMed's reference device with screws cleared with the hexalobe driver

interface design. In summary, the subject device's headed and headless screws will have a hexalobe interface in a variety of diameters and lengths.

The subject device's screws are manufactured from titanium alloy (ASTM F-136), the same material used in the manufacture of the predicate device. This material is biocompatible.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

The OsteoMed ExtremiFix Mini & Small Cannulated Screw System was compared to the predicate device, OsteoMed Headless Cannulated Screw System (K063298). The headed and headless screws underwent verification evaluation to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the OsteoMed ExtremiFix Mini & Small Cannulated Screw System is the same as OsteoMed Headless Cannulated Screw System (K063298).

Performance equivalence was shown through the verification comparison to the predicate device.

Clinical testing is not required to support substantial equivalence.

VIII. CONCLUSIONS

The performance testing data for the subject device, OsteoMed ExtremiFix Mini & Small Cannulated Screw System, demonstrates the subject devices are as safe, as effective, and performs as well as the predicate device (K063298). Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, subject OsteoMed ExtremiFix Mini & Small Cannulated Screw System is substantially equivalent to, and is as safe and as effective as, the legally marketed predicate device, OsteoMed Headless Cannulated Screw System (K063298) under regulation 21 CFR 888.3040, product code HWC.

(End of Summary)