February 24, 2021

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

Re: K203479
Trade/Device Name: ExtremiLOCK Lateral Ankle Fusion Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: November 25, 2020
Received: November 27, 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,

Shumaya Ali, MPH
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203479

Device Name

OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates

Indications for Use *(Describe)*

The OSTEOMED ExtremiLOCK Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the tibia and fibula as well as arthrodesis of the ankle including Tibiotalar and Tibiotalocalcaneal joint. The ExtremiLOCK Ankle Plating System implants are intended for single use only.

The 1/3 tubular plates, hook plates, screws, and washers are also intended for use in trauma, general surgery, and reconstructive procedures of bones appropriate for the size of the device.

The OSTEOMED ExtremiLOCK Ankle Plating System can be used for adult and adolescent (greater than 12-21 years of age) patients.

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.

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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: Andrew "Drew" Johnson

Date Prepared: November 25, 2020

II. DEVICE

Name of the Device:	OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates
Common or Usual Name:	Plate, Fixation, Bone (Primary) and Screw, Fixation, Bone, & Washer
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (Primary) and Smooth or threaded metallic bone fixation fastener
Regulation:	888.3030 (Primary) & 888.3040
Regulatory Class:	II
Product Code:	HRS (Primary) & HWC & HTN

III. PREDICATE DEVICES

Predicate Device: Normed/Zimmer Ankle Fix 4.0, K123347

Additional Predicate: OsteoMed ExtremiLOCK Ankle Plating System, K133691

IV. DEVICE DESCRIPTION

The OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates are a line extension to be included in the OsteoMed ExtremiLOCK Ankle Plating System (previously cleared for market in premarket notification K133691). The OsteoMed ExtremiLOCK Ankle Plating System provides a comprehensive solution for ankle fractures and ankle fusion management. The OsteoMed ExtremiLOCK Ankle Plating System plates, screws, washers and instrumentation are contained in a single instrument

tray. The system instrumentation is used to facilitate plate placement, screw insertion and/or removal of implants.

The OsteoMed ExtremiLock Lateral Ankle Fusion Plates are designed for use in Tibiotalar (TT) and Tibiotalocalcaneal (TTC) arthrodesis procedures through a lateral transfibular approach. The plates feature universal holes that accept angulated locking and standard non-locking 3.5mm and 4.0mm screws and 4.0mm fully threaded cannulated double lead screws. The TT and TTC plates have been designed to optimize compression, strength, and construct stability by providing up to 5 points of fixation in the tibia, talus and calcaneus. The innovative plate design, rounded edges and highly polished surface allows for reduced dissection of soft tissue structures and minimizes soft tissue irritation. Both plates offer multiple compression hole options including oblong holes, transfixation holes, and an anatomic transfixation 5.5mm lag screw compression hole. The 5.5mm transfixation lag screw hole is designed to cross the arthrodesis site within the plate maximizing uniform axial compression across the joint and capturing the medial tibial side.

The OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates are made from commercially pure titanium grade 4 (ASTM F67). The plates are intended for single use only.

V. INDICATIONS FOR USE

The OsteoMed ExtremiLOCK Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the tibia and fibula as well as arthrodesis of the ankle including Tibiotalar and Tibiotalocalcaneal joint. The ExtremiLOCK Ankle Plating System implants are intended for single use only.

The 1/3 tubular plates, hook plates, screws, and washers are also intended for use in trauma, general surgery, and reconstructive procedures of bones appropriate for the size of the device.

The OsteoMed ExtremiLOCK Ankle Plating System can be used for adult and adolescent (greater than 12-21 years of age) patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject device, OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates, and the predicate device use the same fundamental scientific technology. Both devices have similar indications for use and are intended for internal fixation and reconstruction or arthrodesis of the Tibiotalar and Tibiotalocalcaneal bones of the ankle. The subject and predicate devices provide compression through holes or slots and are anatomically designed to proper screw positioning.

The subject device incorporates a similar basic design as compared to the predicate and additional predicate devices. The subject and predicate devices both have compression, locking, and non-locking screw holes or slots and have holes for K-wires. The plate length, width, and thickness of the subject device falls within the ranges for the additional predicate device. The subject and additional predicate devices can be used with similar screw types and diameters and both have variable angle locking screw orientation.

The subject device's plates are manufactured from titanium (ASTM F-67), the same material used in the manufacture of the additional predicate device. This material is biocompatible.

SUMMARY OF NON-CLINICAL TESTING

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

Bench Testing

The evaluation performed (Design performance – bench testing) demonstrates that the OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates are comparable to the predicate device cleared under K123347 and additional predicate device cleared under K133691. The plates underwent verification evaluation (cyclic 4-point bending and static 4-point bending tests were conducted in accordance with Annex A1 of ASTM F382-17) to ensure that the design features met the required mechanical strength criteria for their intended use.

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

Clinical testing is not required to support substantial equivalence.

VII. CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the OsteoMed ExtremiLOCK Lateral Ankle Fusion Plates are as safe, as effective, and perform as well as or better than the legally marketed device, Normed/Zimmer ANKLE FIX and ANKLE Fix Plus (K123347) under regulation 21 CFR 880.3030 (Primary) and 21 CFR 888.3040, product codes HRS (Primary), HWC and HTN.

(End of Summary)