February 22, 2021

Leith Medical LLC
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K200062
Trade/Device Name: Foot and Ankle System
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
Dated: January 21, 2021
Received: January 25, 2021

Dear J.D. Webb:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200062

Device Name
Leith Medical Foot and Ankle System

Indications for Use *(Describe)*
The Leith Medical Ankle Fracture Plates are intended and designed for open reduction, internal fixation of ankle fractures, revision of ankle fractures, as well as osteotomies, and non-unions of the distal tibia and fibula.

The Leith Medical First Tarsal-Metatarsal Joint (1st TMT) Arthrodesis Plates are intended and designed for primary arthrodesis of the 1st TMT joint due to degenerative joint disease and/or hallux valgus, or revision of prior 1st TMT joint arthrodesis.

The Leith Medical Medial Malleolar Fracture Plates are intended and designed for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula.

The Leith Medical First Metatarsal Phalangeal Joint Arthrodesis Plates are intended and designed for primary arthrodesis of the 1st MTP joint due to degenerative joint disease and/or hallux valgus, revision of prior 1st MTP joint arthrodesis, or revision of failed 1st MTP joint implant arthroplasty.

The Leith Medical Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation 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."

*5*10(k) Summary: Leith Medical Foot and Ankle System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	January 12, 2021
Submitted By	Leith Medical LLC 4705 Eagle Feather Dr Austin, TX 78735
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net
Trade Name	Leith Medical Foot and Ankle System
Common Name	bone plate & screws
Classification Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Class	II
Product Code	HRS / HWC
CFR Section	21 CFR section 888.3030 / 888.3040
Device Panel	Orthopedic
Primary Predicate Device	ORTHOLOC 3Di Ankle Plating System – Wright Medical Technology (K102429 / K131093)
Secondary Predicate Devices	ORTHOLOC ® 3Di MTP Fusion Plate / ORTHOLOC® 3Di Foot Reconstruction System – Wright Medical Technology (K152974 / K120359) Small Fragment Set – Stryker (K060514) LCP Anterolateral Distal Tibia Plates / Variable Angle LCP TMT Fusion Plates / 2.4/2.7Synthes 2.7mm/3.5mm Cortex Screw – Synthes (K121601 / K100776 / K112583 ARSENAL Foot Plating System – Trilliant Surgical (K191009)
Device Description	The Leith Medical Foot and Ankle System consists of various shape and size plates for the management of small bone orthopedic osteotomies, reconstruction, and trauma. Features include a low profile, limited contact, a highly radiused edge configuration, capability of dynamic/manual compression. All plates have standard screw holes with a locking feature, and some plates have oval screw holes for compressing the fracture intraoperatively. The system also consists of cortical screw with multiple lengths and diameters.
Materials	Titanium alloy, Ti-6Al-4V (per ASTM F136) Nitinol (per ASTM F2063)

Intended Use	The Leith Medical Foot and Ankle System is intended for use in trauma and reconstructive procedures of the small bones in the hand/foot, ankle, and other bones appropriate for the size of the device.
Substantial Equivalence Claimed to Predicate Devices	The Leith Medical Foot and Ankle System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Leith Medical Ankle Fracture Plates are intended and designed for open reduction, internal fixation of ankle fractures, revision of ankle fractures, as well as osteotomies, and non-unions of the distal tibia and fibula. The Leith Medical First Tarsal-Metatarsal Joint (1st TMT) Arthrodesis Plates are intended and designed for primary arthrodesis of the 1st TMT joint due to degenerative joint disease and/or hallux valgus, or revision of prior 1st TMT joint arthrodesis. The Leith Medical Medial Malleolar Fracture Plates are intended and designed for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula. The Leith Medical First Metatarsal Phalangeal Joint Arthrodesis Plates are intended and designed for primary arthrodesis of the 1st MTP joint due to degenerative joint disease and/or hallux valgus, revision of prior 1st MTP joint arthrodesis, or revision of failed 1st MTP joint implant arthroplasty. The Leith Medical Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.
Summary of the technological characteristics compared to predicate	Intended Use The Leith Medical Foot and Ankle System and the predicate devices are all intended for use in trauma and reconstructive procedures of the small bones in the hand/foot, ankle, and other bones appropriate for the size of the device. Materials The Leith Medical Foot and Ankle System uses the same material as the predicates. Design The Foot and Ankle System and the predicates are equivalent in terms of shape and function. Dimensions The Leith Medical Foot and Ankle System and the predicates are equivalent in their dimensions. Strength The Leith Medical Foot and Ankle System has greater or equivalent strength values compared to the predicates.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic 4-point bending: ASTM F382-17 • Torsional Properties: ASTM F543-17, Annex 1 • Driving Torque: ASTM F543-17, Annex 2 • Axial Pullout: ASTM F543-17, Annex 3 • Bacterial Endotoxins Test (BET): AAMI ST72 • Cyclic Polarization Corrosion Testing: ASTM F2129 • Dynamic Testing of Plate/Ring/Screw Construct

	• Package Performance and Stability Testing The results of these evaluations indicate that the Leith Medical Foot and Ankle System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Leith Medical considers the Leith Medical Foot and Ankle System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use