April 19, 2023

Montross Extremity Medical
% Lee Strnad
President
Intrepid Orthopedics, LLC
3953 Humphrey Road
Richfield, Ohio 44286

Re: K221220
Trade/Device Name: Montross Extremity Medical Hemi Implant System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe Joint Phalangeal (Hemi-Toe) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: February 20, 2023
Received: February 22, 2023

Dear Lee Strnad:

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,

Jesse Muir -S

Jesse Muir, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K221220

Device Name
Montross Extremity Medical Hemi Implant System

Indications for Use *(Describe)*
The Montross Extremity Medical Hemi Implant System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemiarthmoplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock.
Indications include:
- Hallux valgus or Hallux limitus
- Hallux rigidus
- Unstable or painful metatarsallphalangeal (MTP) joint

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

Submitter Information

Applicant: Montross Extremity Medical
20 Belle Air Rd
Colorado Springs, CO, 80906

Contact Person: Lee A. Strnad
Management Representative
Intrepid Orthopedics
3953 Humphrey Rd
Richfield, OH 44286
(440) 465-4321

Date Prepared: 4/28/22

Name of Device: Montross Extremity Medical Hemi Implant System

Common Name: Toe joint phalangeal (hemi-toe) polymer prosthesis

Classification Name: 21 CFR 888.3730 (Hemi-Toe)

Product Code/Panel: KWD/Orthopedic

Predicate Devices: K092047 - Ascension® Metal Great Toe System (Primary Predicate)
K971047 - Futura Biomedical Metal Hemi Toe Implant (Additional Predicate)

Intended Use

The Montross Extremity Medical Hemi Implant System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemiarthroplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock.

Indications for Use

The Montross Extremity Medical Hemi Implant System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemiarthmoplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock.

Indications include:
- Hallux valgus or Hallux limitus
- Hallux rigidus
- Unstable or painful metatarsallphalangeal (MTP) joint

Device Description

The Montross Extremity Medical Hemi Implant System. System consists of a metatarsal component and a phalangeal component (four sizes for each component) designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsal and phalangeal components are used as hemiarthmoplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock. The implants are made from Cobalt Chrome per ASTM F-1537.

Technological Characteristics

The Montross Extremity Medical Hemi Implant System has the same intended use as the predicate devices. The Montross Extremity Medical Hemi Implant System has similar indications for use as the predicate devices. The Montross Extremity Medical Hemi Implant System is manufactured from the same materials as the predicate devices. Montross Extremity Medical Hemi Implant System implants are manufactured from Cobalt Chrome per ASTM F-1537. The range of sizes of the Montross Extremity Medical Hemi Implant System is similar to the predicate devices.

Nonclinical Testing

The following performance testing has been performed:

Bench testing

- Static Pullout
- Dynamic Pullout

The results of this non-clinical testing show that the strength of the Montross Extremity Medical Hemi Implant System is substantially equivalent to the predicate devices for the intended use joint load bearing and can withstand the expected physiologic loads.

510(k) Summary

Sterilization and reprocessing validation

Montross Extremity Medical Hemi Implant System is provided non-sterile and the end user is provided with validated (to establish an SAL of 10^-6) pre-vacuum steam sterilization cycle parameters. The end user is provided with validated reprocessing instructions for the reusable instruments.

Biocompatibility

Biocompatibility assessment was performed on Montross Extremity Medical Hemi Implant System to ensure that the device is biocompatible.

Conclusion

The overall technology characteristics and mechanical performance data lead to the conclusion that the Montross Extremity Medical Hemi Implant System is substantially equivalent to the predicate devices.