May 24, 2019

Nextremity Solutions, Inc.
Greg Denham
Project Leader, Product Development
210 North Buffalo Street
Warsaw, Indiana 46580

Re: K190231
Trade/Device Name: InCore® Lapidus Sterile Kits
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 1, 2019
Received: April 1, 2019

Dear Greg Denham:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Stereotaxic, Trauma
and Restorative 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)*
K190231

Device Name
InCore® Lapidus Sterile Kits

Indications for Use *(Describe)*
The Nextremity Solutions InCore® Lapidus System is a three-part construct intended for internal fixation for First Metatarsocuneiform arthrodesis (also known as Lapidus or First Tarsometatarsal Fusion).

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.

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510(k) Summary

Prepared: February 4, 2019

Submitter: Nextremity Solutions, Inc.
210 North Buffalo Street
Warsaw, IN 46580

Contact: Greg Denham
Project Leader, Product Development
greg.denham@nextremity.com
Phone: 732-383-7901
FAX: 574-966-1396

Proprietary Name: InCore® Lapidus Sterile Kits

Common Name: Bone Screw System

Classification: 21 CFR §888.3040: Smooth or Threaded Metallic Bone Fixation Fastener; Class II

Product Code: HWC

Substantially Equivalent Devices:

- Nextremity Solutions InCore® Lapidus System, K180257

Device Description:

The InCore® Lapidus System consists of a post and two headless compression screws. Posts are available in 28mm and 32mm lengths and in right and left orientations. Screws are available in a 3.5mm diameter and lengths of 24 to 60mm. The post is inserted into the medial cuneiform and compression screws are inserted into the first metatarsal and into the post to maintain apposition of the bones during fusion. A post plug screw is threaded into the top of the post after all components have been implanted to prevent tissue ingrowth into the post and facilitate removal, if needed. All implants are manufactured from color anodized Ti-6Al-4V alloy conforming to ASTM F-136.

The current submission adds disposable instruments to the InCore® Lapidus System. The disposable instruments are packaged in sterile kits with the 28mm post and post plug screw implants. The implant components of the system are unchanged aside from the change in packaging of the 28mm posts and post plug screws.

Intended Use / Indications:

The Nextremity Solutions InCore® Lapidus System is a three-part construct intended for internal fixation for First Metatarsocuneiform arthrodesis (also known as Lapidus or First Tarsometatarsal Fusion).

Summary of Technologies, Similarities/Differences:

The InCore® Lapidus Sterile Kits are substantially equivalent to the predicate device in regards to their intended use and indications, material, design, sizes, and mechanical properties. The implant components of the subject device system are identical to those of the predicate device. While the predicate device was provided with re-usable, non-sterile instruments, the current device system is provided with disposable instruments which are packaged in sterile kits with the 28mm post and post plug implants.

Non-Clinical Testing:

The implant components of the InCore® Lapidus Sterile Kits are identical to the implant components of the predicate device. This submission includes additional, disposable instruments. A biocompatibility risk assessment and packaging validation was completed for the new instruments. Endotoxin testing using the *Limulus* amebocyte lysate (LAL) has been completed. The endotoxin limit is <10 EU total.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the InCore® Lapidus Sterile Kits to the predicate device.

Conclusions / Substantial Equivalence:

Differences between the subject device system and the predicate device system do not raise new types of safety and effectiveness questions. InCore® Lapidus Sterile Kits are substantially equivalent to the predicate device in regards to its intended use, material, design, sizes and mechanical properties.