April 25, 2018

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

Re: K180257
Trade/Device Name: InCore® Lapidus System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 29, 2018
Received: January 30, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K180257

Device Name

InCore® Lapidus System

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Prepared: April 8, 2018

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 System

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:

- Extremity Medical Screw and Washer System (IO FiX), K121349 – Primary Predicate
- Phalanx Innovations OsteoBullet Compression Screw, K160304
- Nextremity Solutions Axi+Line Proximal Bunion Correction System, K152548 – Reference Predicate

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 system is provided with a set of accessory instruments designed for preparation of the implant site and insertion of the implants into bone.

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 System is similar to the predicate devices in regards to its intended use and indications, material, design, sizes, and mechanical properties. Differences between the subject device system and the predicate device systems include a targeting guide and sub-cortical interlocking components. These differences do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

To evaluate the strength of the InCore® Lapidus System and components, axial pull-out strength, torque to failure and 3 point bend tests were performed on worst case compression screws. Torque to failure, static 3 point bend and dynamic 3 point bend tests were performed on worst case constructs. These tests confirmed that the strength of the InCore® Lapidus System is substantially equivalent to predicate devices with similar indications and is adequate for its intended use. In addition, bacterial endotoxin levels were measured using LAL testing.

Clinical Testing:

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

Conclusions / Substantial Equivalence:

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