DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 13, 2017

Additive Orthopaedics, LLC
Greg Kowalczyk
President
83 Amelia Circle
Little Silver, New Jersey 07739

Re: K170214
Trade/Device Name: Additive Orthopaedics Locking Lattice Plate
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 23, 2017
Received: March 23, 2017

Dear Greg Kowalczyk:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170214

Device Name

Additive Orthopaedics Locking Lattice Plate

Indications for Use *(Describe)*

The Additive Orthopaedics Locking Lattice Plate is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle.

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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510K Summary
(Per 21 CFR 807.92)

General Company Information:

Additive Orthopaedics, LLC.
Gregory Kowalczyk
President
83 Amelia Circle
Little Silver, NJ 07739
Phone: (732) 882-6633
greg@additiveorthopaedics.com

Date Prepared: March 29, 2017

General Device Information:

Proprietary Name: Additive Orthopaedics Locking Lattice Plate

System Classification:

Common Name: Plate, Fixation, Bone

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories;
Product Code: HRS- Class II
Classification Name and Reference: 21 CFR 888.3030

Regulation Name: Smooth or Threaded metallic bone fixation fastener and accessories;
Product Code: HWC- Class II
Classification Name and Reference: 21 CFR 888.3040

Predicate Devices:

Company	Product Name	510K Number
Primary: Nextremity Solutions, Inc.	Restore Fixation System	K131061
Additional: Paragon 28, Inc.	Paralock Plating System	K140397
Reference: Additive Orthopaedics, LLC	Hammertoe Correction System	K153207
Reference: Additive Orthopaedics, LLC	Bone Wedge System	K160264

Description

The Additive Orthopaedics Lattice Locking Plates consist of a plate and locking and non-locking screws with surgical site preparation and insertion instruments. It is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle. The plates are additively manufactured from medical grade titanium alloy (Ti-6AL-4V Eli). The screws are manufactured from medical grade titanium alloy. (Ti-6AL-4V Eli). The implants are provided sterile and intended for single use only. The locking lattice plate and screws come in multiple sizes.

Intended Use (Indications)

The Additive Orthopaedics Locking Lattice Plate is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle.

(a) (6) Technological Characteristics Comparison
The Additive Orthopaedics Locking Lattice Plate and the legally marketed predicated devices have similar indications, dimensions, geometry, materials and manufacturing process. The Additive Orthopaedics Locking Lattice Plate is technologically substantially equivalent to the predicate devices.

(b) (1) Substantial Equivalence- Non-Clinical Evidence
Mechanical testing including 4 point bending (static and dynamic) per ASTM F382 as well as static torsion, static driving torque and removal torque, and static axial pullout per F543 for the proposed device. Bacterial endotoxin levels on the device were also evaluated by LAL pyrogen testing. Pyrogen levels for the device system were below the 20 EU/device limit.
The results of these verification activities demonstrate that the Additive Orthopaedics Locking Lattice Plate is substantially equivalent to the predicate device identified.

(b) (3) Substantial Equivalence - Conclusions
The Additive Orthopaedics Locking Lattice Plate possesses the same technologic characteristics of the predicate devices. These characteristics include the intended use, basic design, material, manufacturing process, size and fundamental technology. The design characteristics of the subject system raises no new safety and effectiveness questions. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.