January 10, 2019

Additive Orthopaedics
Gregory Kowalczyk
President
44 Riverdale Ave
Monmouth Beach, New Jersey 07750

Re: K183011
Trade/Device Name: Additive Orthopaedics Patient Specific 3D Locking Lattice Plates
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: October 30, 2018
Received: October 31, 2018

Dear Gregory 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. 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 -S

for
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)*

K183011

Device Name

Additive Orthopaedics Patient Specific 3D Lattice Locking Plates

Indications for Use *(Describe)*

The Additive Orthopaedics Patient Specific 3D Printed Locking Lattice Plate is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle. It is a patient specific 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.

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Additive Orthopaedics, LLC December 28, 2018
Patient Specific 3D Locking Lattice Plates

510K Summary (Per 21 CFR 807.92)

General Company Information:

Additive Orthopaedics, LLC.
Gregory Kowalczyk
President

44 Riverdale Ave

Monmouth Beach, NJ 07750
Phone: (732) 882-6633
greg@additiveorthopaedics.com

Date Prepared: December 28, 2018

General Device Information:

Proprietary Name: Additive Orthopaedics Patient Specific 3D Printed Locking Lattice Plates

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

Predicate Devices:

Primary Predicate Device:

Company	Product Name	510K Number
Additive Orthopaedics	Locking Lattice Plates	K170214

Additional Predicate Device:

Company	Product Name	510K Number
BIOPRO, INC.	BioPro Foot Plating System	K162674

Reference Device:

Company	Product Name	510K Number
Additive Orthopaedics	Patient Specific 3D Printed Bone Segments	K180239

The predicate devices have not been the subject of any design related recall.

Device Description
The Additive Orthopaedics Patient Specific 3D Printed Locking Lattice Plate is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle. This is a patient specific device which utilizes the CT scanning protocol previously cleared in K180239 by Additive Orthopaedics. These patient specific devices are manufactured within a size range of 30-80mm and are supplied non-sterile.

The subject device is manufactured from medical grade titanium alloy Ti-6Al-4V ELI and allows the surgeon to align and stabilize small bone osteotomies such as MPJ fusions, calcaneal osteotomies, Evans Osteotomies, opening wedge osteotomies and others. The plate is fixated using both locking and non-locking screws which were cleared in K163593 (Additive Orthopaedics) and compatible with Additive Orthopaedics wedges (K153207 and K180239).

Indications for Use
The Additive Orthopaedics Patient Specific 3D Locking Lattice Plate is indicated for alignment, stabilization and fusion of fractures, osteotomies and arthrodesis of small bones such as the foot and ankle. This is a patient specific device.

Comparison of Technological Characteristics with the Predicate Device

Technological Characteristics Comparison
The Additive Orthopaedics Patient Specific 3D Locking Lattice Plate and the legally marketed predicate devices have similar indications, geometry, materials and manufacturing process. The subject device uses similar technology as the predicate to manufacture the plates. The difference is that the subject device is patient specific and the dimensions and geometry shall fall within the size ranges of 30-80mm. The dimensions and geometry of the Patient Specific 3D Printed Locking Lattice plates are patient specific, utilizing a previously cleared CT scanning protocol (K180239).

Substantial Equivalence Non-Clinical Evidence
The device is manufactured using similar materials and manufacturing methods to the predicate device. The only difference is that the plates are manufactured for a specific patient using previously cleared CT scan protocols. 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 were conducted on the predicate device and may be referenced in K170214.

Substantial Equivalence --- Conclusions
The Additive Orthopaedics Patient Specific 3D Locking Lattice Plates have similar technologic characteristics of the predicate devices. These characteristics include the basic design, material, manufacturing process, size and fundamental technology. The differences between the subjected device and the predicate are the intended use. Specifically, the subject device is a patient specific device. 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 the same as the predicate device.