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

May 16, 2018

Re: K180239
Trade/Device Name: Additive Orthopaedics Patient Specific 3D Printed Bone Segments
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: April 13, 2018
Received: April 16, 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. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180239

Device Name
Additive Orthopaedics Patient Specific 3D Printed Bone Segments

Indications for Use *(Describe)*
The Additive Orthopaedics 3D Printed Bone Segments are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

*Cotton (opening wedge) osteotomies of the medial cuneiform
*Evans lengthening osteotomies

The Additive Orthopaedics 3D Printed Bone Segments are intended for use with ancillary

plating fixation. The Additive Orthopaedics 3D Printed Bone Segments are not intended for

use in the spine.

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.

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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@additiveortho.com

Date Prepared: April 12, 2018

General Device Information:

Proprietary Name: Additive Orthopaedics Patient Specific 3D Printed Bone Segments

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

Predicate Devices:

Company	Product Name	510K Number
Primary: Additive Orthopaedics, LLC	Bone Wedge System	K153207
Reference: BioArchitects	Patient Specific Cranial Plate	K151692
Materialise N.V.	TruMatch CMF Titanium 3D Printed Implant System	K170272
Materialise N.V.	Mimics	K073468

Description

The Additive Orthopaedics Patient Specific 3D Printed Bone Segments is a simple one piece device constructed individually for each patient using CT image data. It is intended to be used for internal bone fixation for bone fractures or osteotomies in the foot and ankle. The

segments are additively manufactured from medical grade titanium alloy (Ti-6AL-4V Eli). It is a patient specific device. The bone segments come in a variety of configurations that depend on the geometry of the application. The surgeon approves the design of the 3D Printed Bone Segments by comparing his/her design requirements to engineering drawings prior to the construction of the implant device.

Intended Use (Indications)

The Additive Orthopaedics 3D Printed Bone Segments are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

*Cotton (opening wedge) osteotomies of the medial cuneiform
*Evans lengthening osteotomies

The Additive Orthopaedics 3D Printed Bone Segments are intended for use with ancillary plating fixation.

The Additive Orthopaedics 3D Printed Bone Segments are not intended for use in the spine.

It is a patient specific device.

(a) (6) Technological Characteristics Comparison
The Additive Orthopaedics Patient Specific Bone Segments and the legally marketed predicate device have nearly identical indications, identical materials and identical manufacturing processes. The dimensions and geometry of the subject device, however, are patient-specific. The dimensions and geometry of the Additive Orthopaedics Patient Specific Bone Segments fall within the range of sizes already claimed for the predicate device, are developed in a process equivalent to the reference device, and are verified by the surgeon.

(b) (1) Substantial Equivalence- Non-Clinical Evidence
Morphological characterization, mechanical testing (including, friction, roughness, durability/abrasion, and compressive fatigue) as well as biocompatibility testing were performed on the predicate device and compared to the Additive Orthopaedics Patient Specific Bone Segments. The results of these comparison activities demonstrate that the Additive Orthopaedics Patient Specific Bone Segments are identical to the predicate device identified.

(b) (3) Conclusion- Substantial Equivalence
The Additive Orthopaedics Patient Specific Bone Segments possess the same technologic characteristics of the predicate devices. These characteristics include the intended use, basic design, material, size and fundamental technology. The design characteristics of the subject system do not raise any new types of questions of safety and effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.