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

September 7, 2016

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

Re: K153207
Trade/Device Name: Additive Orthopaedics Bone Wedge System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 29, 2016
Received: August 5, 2016

Dear Mr. 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 Parts 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" (21CFR 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)*
K153207 (page 1 of 1)

Device Name
Additive Orthopaedics Bone Wedge System

Indications for Use *(Describe)*
The Additive Orthopaedics Bone Wedges 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 Bone Wedges are intended for use with ancillary plating fixation.

The Additive Orthopaedics Bone Wedges are not intended for use in the spine.

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: September 7, 2016

General Device Information:

Proprietary Name: Additive Orthopaedics Bone Wedge System

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

Predicate Devices:

Company	Product Name	510K Number
Primary: Integra, Inc.	Integra Titanium Bone Wedges	K131360
Additional: 4-Web, Inc.	Web Osteotomy Bone Wedge	K130185

Description

The Additive Orthopaedics Bone Wedge System is a series of wedge-shaped devices intended to be used for internal bone fixation for bone fractures or osteotomies in the foot and ankle. The wedges are additively manufactured from medical grade titanium alloy (Ti-6AL-4V Eli). The implants are provided sterile and intended for single use only. The wedges come in 18 individual sizes and configurations to correct various skeletal deformities in the foot. The Additive Orthopaedics Bone Wedge System is intended to be used with ancillary plating fixation.

Intended Use (Indications)

The Additive Orthopaedics Bone Wedges 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 Bone Wedges are intended for use with ancillary plating fixation.

The Additive Orthopaedics Bone Wedges are not intended for use in the spine.

(a) (6) Technological Characteristics Comparison
The Additive Orthopaedics Bone Wedge System and the legally marketed predicated devices have similar indications, dimensions, geometry and materials. The Additive Orthopaedics Bone Wedge System is technologically substantially equivalent to the predicate devices.

(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 proposed device. The results of these verification activities demonstrate that the Additive Orthopaedics Bone Wedges are substantially equivalent to the predicate device identified.

(b) (3) Substantial Equivalence
The Additive Orthopaedics Bone Wedge System possesses 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.