DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 1, 2016

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

Re: K160264
Trade/Device Name: Additive Orthopaedics Hammertoe Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: April 28, 2016
Received: May 2, 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 yours,

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)*

K160264

Device Name

Additive Orthopaedics Hammertoe Correction System

Indications for Use *(Describe)*

The Additive Orthopaedics Hammertoe Correction System is indicated for fixation of fractures, and fusion of small bones in the foot and hand; where such fragments are not under tension or load-bearing.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) 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: May 23, 2016

General Device Information

Proprietary Name: Additive Orthopaedics Hammertoe Correction System

Classification: **Common Name**: Smooth or threaded metallic bone fixation fastener
Product code: HTY- Class II
Classification Name and Reference: 21 CFR 888.3040

Predicate Devices

Primary:

- Arthrex, Inc. — Arthrex Bio-Pin (Marketed as Arthrex Trim-It™ Spin Pin) [510(k) K050259]

Addional Predicates:

- MedShape, Inc. — Medshape FastForward (Marketed as MedShape Button) [510(k) K141420]
- Synchro Medical, Inc. — Synchro Medical (Marketed as ToeGrip) [510(k) K133477]

Description
The Additive Orthopaedics Hammertoe Correction System is a monoblock non-circular shaft implant that is cannulated and non-cannulated and incorporates barbs along its longitudinal axis. The system is provided with a drill designed for preparation of the implant site. The implant device, and the drill, are provided in a sterile procedure pack. The implant is intended for single use only and it is available in 0° and 10° configurations. The implant device is additively manufactured from medical grade titanium alloy (Ti-6Al-4V).

Intended Use (Indications)
The Additive Orthopaedics Hammertoe Correction System is indicated for fixation of fractures, and fusion of small bones in the foot and hand; where such fragments are not under tension or load-bearing.

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

(b) (1) Substantial Equivalence- Non-Clinical Evidence
Mechanical testing was performed as described in relevant recognized standards, including testing for pull-out force, static and dynamic flexion extension resistance.

(b) (3) Substantial Equivalence
The Additive Orthopaedics Hammertoe Correction 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.