Additive Device, Inc. (ADI) d/b/a restor3d
Nathan Evans
Vice President of Technology and Strategy
311 W Corporation Street
Durham, North Carolina 27701

November 5, 2019

Re: K191047
Trade/Device Name: ADI TiDAL Osteotomy Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PLF
Dated: October 3, 2019
Received: October 4, 2019

Dear Nathan Evans:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K191047

Device Name
ADI TiDAL Osteotomy Wedge

Indications for Use *(Describe)*
The TiDAL Osteotomy 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 TiDAL Osteotomy Wedges are intended for use with ancillary plating fixation.

The TiDAL Osteotomy 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Additive Device Incorporated

510(k) Summary

510(k) Number: K191047

Date Prepared: October 31, 2019

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

Additive Device, Inc. (ADI) d/b/a restor3d
311 W Corporation St
Durham, NC 27701
984-888-0593

B. Company Contact:

Nathan Evans, Ph.D.
VP of Technology and Strategy
404-660-4418
nathan@restor3d.com

C. Device Information:

Trade Name: ADI TiDAL Osteotomy Wedge
Common Name: Osteotomy Wedge

D. Classification: Orthopedic, Bone Wedge (Class II)
21 CFR 888.3030

E. Predicate Device(s):

Integra Titanium Bone Wedge®, K131360

F. Physical Description:

The proposed ADI TiDAL Osteotomy Wedge is a sterile, single use medical grade titanium alloy (Ti-6Al-4V) device, available in varied footprints and heights. The ADI TiDAL Osteotomy Wedge is intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as Cotton (opening) osteotomies of the medical cuneiform and Evans (lengthening) osteotomies. The TiDAL Wedge device is comprised of a single, continuous piece of titanium alloy fabricated via additive manufacturing. The ADI device has a porous structure throughout the body of the implant and a circular window for the packing of graft material, a threaded hole for insertion (Evans implant only), and a strike plate for implant positioning.

G. Indications for Use:

The TiDAL Osteotomy 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 TiDAL Osteotomy Wedges are intended for use with ancillary plating fixation.

The TiDAL Osteotomy Wedges are not intended for use in the spine.

H. Performance Testing

The proposed ADI device was subjected to the following performance tests to support the assertion of substantial equivalence*:*

- Comparative functional performance testing per ASTM F2077-18, Test Methods For Intervertebral Body Fusion Devices;
  - Static compressive strength
  - Dynamic compressive strength
  - Static compression shear strength
- Comparative wear analysis following dynamic compression
- Expulsion testing

I. Comparison of Characteristics / Substantial Equivalence:

Although the ADI TiDAL Osteotomy Wedge differs from the predicate in the device material, the devices have similar design / physical characteristics (i.e., porous metal implant with graft window) and the same intended use.

The ADI TiDAL Osteotomy Wedge does not raise different questions of safety or effectiveness. The ADI TiDAL Osteotomy Wedge is substantially equivalent to the predicate device (Integra Titanium Bone Wedge®, K131360).