June 17, 2021

restor3d, Inc.
Michaela Pigue
R&D Engineer
311 W Corporation St
Durham, North Carolina 27701

Re: K201314
Trade/Device Name: Restor3d Utility 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: June 10, 2021
Received: June 14, 2021

Dear Michaela Pigue:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201314

Device Name
restor3d Utility Wedge

Indications for Use *(Describe)*
The restor3d Utility Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Metatarsal Cuneiform osteotomies
- Nonunion of arthrodesis of the Midfoot including Metatarsal Cuneiform osteotomies (TMT or Lapidus)
- Hindfoot osteotomies such as Ankle fusion and Subtalar fusion

The restor3d Utility Wedges are intended for use with supplemental fixation.
The restor3d Utility 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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510(k) Summary

510(k) Number: K201314

Date Prepared: 6/10/2021

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

A. Submitter:
restor3d, Inc.
311 W Corporation St
Durham, NC 27701
984-888-0593

B. Company Contact:
Michaela Pigue
R&D Engineer
984-888-0593
michaela@restor3d.com

C. Device Information:
Trade Name: restor3d Utility Wedge
Common Name: Osteotomy Wedge

D. Classification: Orthopedic, Bone Wedge

21 CFR 888.3030

Product Code: PLF

Predicate Device(s):

ADI TiDAL Osteotomy Wedge, K191047, Primary Predicate

Product Code: PLF

4Web Osteotomy Truss System, K172294, Additional Predicate

Product Code: HRS

E. Physical Description:
The proposed Utility Wedge is a sterile, single use medical grade titanium alloy (Ti-6Al-4V) device, available in varied footprints and heights, designed for opening and lengthening osteotomy procedures of the foot, including Lapidus and Subtalar.

F. Indications for Use:

The restor3d Utility Wedges are intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
- Opening wedge of Medial Cuneiform or Cotton osteotomies
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
- Metatarsal Cuneiform osteotomies
- Nonunion of arthrodesis of the Midfoot including Metatarsal Cuneiform osteotomies (TMT or Lapidus)
- Hindfoot osteotomies such as Ankle Fusion and Subtalar Fusion

The restor3d Utility Wedges are intended for use with supplemental fixation. The restor3d Utility Wedges are not intended for use in the spine.

G. Comparison of Characteristics / Performance Testing / Substantial Equivalence:

The restor3d Utility Wedge is substantially equivalent to the primary predicate device (ADI TiDAL Osteotomy Wedge, K191047) in important physical and performance specifications and the reference predicate device (4 Web Osteotomy Truss System, K172294) in intended use. The devices have similar design/physical characteristics (i.e., similar sizing and mechanism of fixation) and the same indications for use. The proposed restor3d device was subject to the following benchtop performance tests to support the assertion of substantial equivalence:

- Static Compressive Strength
- Dynamic Compressive Strength
- Expulsion

H. Conclusions:

No new questions of safety or effectiveness were identified during device testing; therefore, the restor3d Utility Wedge is considered substantially equivalent to the predicate device.

6/10/2021

Michaela Pigue
R&D Engineer
984-888-0593
michaela@restor3d.com