January 4, 2022

restor3d
Lexi Lewis
Director of Extremity
311 West Corporation Street
Durham, North Carolina 27701

Re: K211789
Trade/Device Name: restor3d Pin Implants
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: December 3, 2021
Received: December 7, 2021

Dear Ms. Lewis:

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,

Colin O’Neill, MBE
Assistant Director
DHT6B: Division of Spinal 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)*
K211789

Device Name
restor3d Pin Implants

Indications for Use *(Describe)*
restor3d Pin Implants are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis, and bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

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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510(k) Summary

510(k) Number: K211789

Date Prepared: December 3, 2021

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

A. 510(k) Submitter:
restor3d, inc.
311 W. Corporation St.
Durham, NC 27701

B. Primary Correspondent:
Lexi Lewis
Director of Extremity
317-287-4311
lexi@restor3d.com

C. Device Information:
Trade Name: restor3d Pin Implant
Common Name: fixation, pin, smooth

D. Classification:
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Class: Class II
Product Code: HTY

E. Predicate Devices:
Primary Predicate: OSSIO™ Pin Product Family (K181180)
Reference Predicates: Arthrex Bio-Pin (K050259)
ADI TiDAL Osteotomy Wedge (K191047)
Zimmer Kirschner Wires and Steinmann Pins (K143618).

F. Physical Description:
restor3d pin implants are made from implant grade titanium alloy using an additive manufacturing process and possess a porous surface structure of unique topology. Pin

implants are designed for use in a variety of surgical procedures including fixation of fractures, osteotomies, arthrodesis and as bone graft in the presence of additional immobilization. The pin implants are offered in a range of diameters, permitting surgeons to choose a relevant size for the affected anatomy.

G. Indications for Use:
restor3d Pin Implants are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodesis, and bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

H. Comparison of Characteristics / Performance Testing / Substantial Equivalence:
The restor3d Pin Implants are substantially equivalent to the predicate devices in intended use and performance specifications. 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:

- Bending Testing
- Shear Testing
- Pullout Testing

No new questions of safety or effectiveness were identified during device testing; therefore, the restor3d Pin Implants are considered substantially equivalent to the predicate devices.

A. Lewis

Date: Dec. 3, 2021

Lexi Lewis
Director of Extremity
lexi@restor3d.com