May 25, 2022

Restor3d, Inc.
Jillian Udell
Product Manager
311 W Corporation St
Durham, North Carolina 27701

Re: K201393
Trade/Device Name: restor3d MTP Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe Joint Phalangeal (Hemi-Toe) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: May 16, 2022
Received: May 18, 2022

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,

Ting Song, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K201393

Device Name
restor3d MTP Implant

Indications for Use *(Describe)*
The restor3d MTP Implant is intended for use as a hemi-arthroplasty implant for the first metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint. The device is a single use implant intended to be press fit with optional use of bone cement.

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: K201393

Date Prepared: May 16, 2022

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:
Jillian Udell
Product Manager
984-888-0593
jillian@restor3d.com

C. Device Information:

Trade Name:	restor3d MTP Implant
Common Name:	MTP Arthroplasty Implant

D. Classification: MTP Arthroplasty Implant
21 CFR 888.3730

E. Predicate Device(s):
Metatarsal Decompression Implant™, K090127

F. Physical Description:
The restor3d MTP Implant is a sterile, single use implant grade metal device, available in varied articulating surface coverages. The restor3d MTP implant is designed to replace damaged articulating surface of the first metatarsal distal head. The device is intended for the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock and integrity of the first metatarsal head. This implant can also be used in the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The implant is a single use product intended to be press fit, with optional use of bone cement.

The restor3d MTP Implant is comprised of a single laser powder bed fusion (LPBF) printed cobalt-chromium alloy (Co28Cr6Mo) part. The external surface of the implant that is intended to be in contact with the phalanx is mirror polished.

G. Indications for Use:

The restor3d MTP Implant is intended for use as a hemi-arthroplasty implant for the first metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint. The device is a single use implant intended to be press fit, with optional use of bone cement.

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

The restor3d MTP Implant is substantially equivalent to the predicate device (Metatarsal Decompression Implant™, K090127) in intended use and important physical and performance specifications. The devices have similar design / physical characteristics (i.e., similar articulating surface, presence of stem) and similar indications for use. The proposed restor3d device was subjected to the following performance tests to support the assertion of substantial equivalence*:*

- Comparative monotonic compression-subsidence test
- Monotonic compression test
- Comparative monotonic bending-pullout test
- Monotonic bending test
- Surface roughness analysis
- Monotonic shear, shear fatigue, and abrasion tests for modified metallic surfaces
- Gravimetric and comparative particulate analysis tests

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

Jillian Udell 05/16/2021

Jillian Udell
Product Manager

984-888-0593
jillian@restor3d.com