August 3, 2023

restor3d
Anika Moorjani
Regulatory Engineer
311 West Corporation Street
Durham, North Carolina 27701

Re: K231458
Trade/Device Name: Extremity Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: May 19, 2023
Received: May 19, 2023

Dear Anika Moorjani:

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,

Limin Sun -S

Limin Sun, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231458

Device Name
Extremity Staple

Indications for Use *(Describe)*
The Extremity Staple System is indicated for use in fracture, osteotomy fixation and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that preclude staple placement). The device is intended for use in short, long, or flat bones. The Extremity Staple System is intended for single use only.

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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Traditional 510(k)

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510(k) Summary

Date Prepared: August 2nd, 2023

The purpose of this submission is to seek clearance for a new device. This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. 510(k) Sponsor:

restor3d, inc.
311 W. Corporation St.
Durham, NC 27701

B. Primary Correspondent:

Anika Moorjani
Regulatory Engineer
anika@restor3d.com
(501) 240-3476 (direct)

C. Premarket Notification:

Trade Name:	Extremity Staple
Common Name:	Staple, Fixation, Bone
Classification Name:	Single/Multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	JDR
Classification:	II

D. Indications for Use:

The Extremity Staple System is indicated for use in fracture, osteotomy fixation, and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that preclude staple placement). The device is intended for use in short, long, or flat bones. The Extremity Staple System is intended for single use only.

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E. Predicate Devices:

The Extremity Staple is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K142292	BME Speed™ Implant	BioMedical Enterprises, Inc. (DePuy Synthes)
Reference Predicate Device		
K072298	BioPro Memory Staple	BioPro Inc.

F. Device Description:

The Extremity Staple System, which consists of the Extremity Staple and associated instruments, is intended for use for fixation and compression and supports several surgical techniques (e.g., fracture, osteotomy, joint arthrodesis, and fixation of bone fragments). The staples are made of implant-grade Nitinol and are designed to exhibit superelastic properties at room temperature. This allows for continued compression to be applied across bone segments, thus enhancing long-term stability and promoting fusion. Each staple is pre-loaded on an inserter for implantation and sterile packed. The staples are available in multiple sizes, varying by bridge length and leg length, to accommodate individual patient anatomy. Disposable Instrumentation is provided to assist in the surgical placement of the Extremity Staple.

G. Comparison of Characteristics and Intended Use:

The proposed Extremity Staple System is substantially equivalent to the primary predicate, BME Speed™ Implant in material, design, technological characteristics, product features, and mechanical performance. The proposed Extremity Staple, primary predicate, and reference predicate, the BioPro Memory Staple, are all manufactured from the same nitinol material per ASTM F2063-18. The proposed Extremity Staple and primary predicate share similar features such as the natural arc on the bridge to match the contour of bones and barbs on the legs to increase pullout strength. The proposed Extremity Staple differs from the primary predicate in that it features round legs to match the profile of the drill holes, whereas the primary predicate features square legs. The

proposed Extremity Staple sizes fall within the bounds of the primary and reference predicates.

The proposed Extremity Staple System is also substantially equivalent to the primary predicate, BME Speed™ Implant in intended use. The proposed Extremity Staple and primary predicate, the BME Speed™ Implant, are both intended for use for fracture, osteotomy fixation, joint arthrodesis, and fixation of bone fragments. The primary predicate, the BME Speed™ Implant, includes specific examples of long, short, and flat bones where the staple may be used, which are representative of the intended use for the Extremity Staple. These changes in indications do not impact the intended use of the proposed Extremity Staple when compared to the primary predicate, The BME Speed™ Implant.

H. Performance Testing:

The proposed Extremity Staple was subjected to the following mechanical performance tests to support the assertion of substantial equivalence:

- Static Four Point Bend Testing per ASTM F564-17 (FDA Recognition Number #11-325)
- Dynamic Four Point Bend Testing per ASTM F564-17 (FDA Recognition Number #11-325)
- Static Pull-out Testing per ASTM F564-17 (FDA Recognition Number #11-325)
- Cyclic Corrosion Testing per ASTM F2129-19a (FDA Recognition Number #8-522)

The results of this non-clinical testing demonstrate that the mechanical performance of the Extremity Staple is sufficient for its intended use and no new questions of safety or effectiveness were identified during device testing; therefore, the Extremity Staple is considered substantially equivalent to the BME Speed™ predicate device.

I. Conclusions:

The Extremity Staple was shown to be substantially equivalent in performance and has similar technological characteristics as the BME Speed™ predicate through comparison in areas including design, intended use, implant materials, product features, mechanical performance, and function. Based on the data submitted, the Extremity Staple does not raise any new questions about safety or effectiveness. Therefore, it can be concluded that the Extremity Staple is substantially equivalent to the predicate device.