restor3D
Nathan Evans
VP of Technology and Strategy
311 W Corporation St
Durham, North Carolina 27701

March 19, 2020

Re: K193491/S001
Trade/Device Name: restore3d Metallic Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 16, 2019
Received: December 17, 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,

Jesse Muir, Ph.D.
Acting 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)*
K193491

Device Name
restor3d Metallic Interference Screw

Indications for Use *(Describe)*
The restor3d Metallic Interference Screw is used to provide bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

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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restor3d, inc.

510(k) Summary

510(k) Number: K193491

Date Prepared: 3/13/2020

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

C. Device Information:
Trade Name: restor3d Metallic Interference Screw
Common Name: Interference Screw

D. Classification: Smooth or threaded metallic bone fixation fastener
21 CFR 888.3040

E. Predicate Device(s):
Conmed EZ-Start Interference Screw (K182955)
Smith&Nephew CANNU-FLEX SILK Interference Screw (K921481)

F. Physical Description:
The proposed restor3d Metallic Interference Screw is a sterile, single use implant available in either titanium alloy or cobalt chrome alloy. The device is cannulated to allow a guidewire to assist with placement of the screw into the bone tunnel. The screw is used to maintain fixation of bone-tendon-bone grafts in orthopedic procedures.

G. Indications for Use:

The restor3d Metallic Interference Screw is used to provide bone-tendon-bone graft fixation in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction of the knee.

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

The restor3d Metallic Interference Screw is substantially equivalent to the predicate devices (Conmed EZ-Start Interference Screw, K182955, and Smith&Nephew CANNU-FLEX SILK Interference Screw, K921481) in intended use and important physical and performance specifications. The devices have similar design / physical characteristics (i.e., similar sizing and mechanism of fixation) and the same indications for use. In addition, the restor3d Metallic Interference Screw is available with a rounded head feature, and may be provided in packaging which differs from the predicate devices. The proposed restor3d device was subjected to the following performance tests to support the assertion of safety and substantial equivalence to the predicate devices:

- Pullout Strength
- Insertion Torque
- Biocompatibility [ISO 10993-1]
- Pyrogenicity [ANSI/AAMI ST72]
- Sterilization [ISO 11137-1, ISO 11137-2, and AAMI TIR33]

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

3/13/2020

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