March 24, 2025

restor3d, Inc.
Brianna Prindle
Director of Regulatory Affairs
4001 NC-54 Hwy, Suite 3160
Durham, North Carolina 27709

Re: K242356
Trade/Device Name: TIDAL Fusion Cage System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: SAI, HSB
Dated: August 8, 2024
Received: February 20, 2025

Dear Brianna Prindle:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.03.24 18:58:58 -04'00'

Farzana Sharmin, 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)*
K242356

Device Name
TIDAL Fusion Cage System

Indications for Use *(Describe)*
The TIDAL Fusion Cage System is intended to be used as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The TIDAL Fusion Cage System is intended for use as an accessory to the DynaNail TTC Fusion System. The TIDAL Fusion Cage System is not intended for standalone use. The TIDAL Fusion Cage System is intended for use with autograft and/or allogenic bone graft.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date Prepared: March 24, 2025

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

A. 510(k) Owner:

restor3d, inc.
4001 NC-54 Hwy, Suite 3160
Durham, NC 27709

B. Primary Correspondent:

Brianna Prindle
Director of Regulatory Affairs
brianna@restor3d.com
786-521-0501

C. Premarket Notification:

Submission Type:	Traditional 510(k)
Trade Name:	TIDAL Fusion Cage System
Classification Name:	Single/multiple components metallic bone fixation appliances and accessories
Common Name:	Intramedullary fixation rod
Regulation Number:	21 CFR 888.3020
Product Code:	SAI, HSB
Classification:	II

D. Indications for Use:

The TIDAL Fusion Cage System is intended to be used as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The TIDAL Fusion Cage System is intended for use as an accessory to the DynaNail TTC Fusion System. The TIDAL Fusion Cage System is not intended for standalone use. The TIDAL Fusion Cage System is intended for use with autograft and/or allogenic bone graft.

E. Predicate Devices:

The TIDAL Fusion Cage System is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K171376	DynaNail TTC Fusion System	MedShape
Secondary Predicate Device		
K230088	4WEB Medical Ankle Truss System (ATS)	4WEB
Reference Predicate Device		
K201314	restor3d Utility Wedge	restor3d

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F. Device Description:

The subject TIDAL Fusion Cage System is a single-use, implant grade titanium alloy (Ti-6Al-4V) device, available in varying shapes, heights and diameters, designed to be used as an accessory to the DynaNail TTC System for ankle fusion.

G. Comparison of Technology

The subject TIDAL Fusion Cage System and predicate DynaNail TTC Fusion System have the same intended use for tibiotalocalcaneal (TTC) fusion. The indications for use of the TIDAL Fusion Cage System are a subset of the indications for use for the predicate DynaNail TTC Fusion System (K171376). The subject TIDAL Fusion Cage System is intended to be an accessory to the primary predicate DynaNail TTC Fusion System. The technological characteristics of the TIDAL Fusion Cage System differ from the predicate device, specifically, the material and manufacturing methods. The intended use, technological characteristics, materials and manufacturing of the subject TIDAL Fusion Cage System are identical to the secondary predicate device, the 4WEB Medical Ankle Truss System (ATS) (K230088). Both the subject device and reference device are made of titanium alloy (Ti-6Al-4V) and are manufactured using an additive manufacturing method.

H. Comparison of Non-Clinical Performance

The TIDAL Fusion Cage System is substantially equivalent to the predicate device (DynaNail TTC Fusion System, K171376) in intended use, indications for use and performance specifications. The subject TIDAL Fusion Cage System is used as an accessory to the DynaNail TTC Fusion System, with a central clearance hole to accommodate the nail and porosity for packing of graft material. The subject TIDAL Fusion Cage System was subject to the following benchtop and clinical performance tests to support the assertion of substantial equivalence:

- Static Compressive Strength
- Dynamic Compressive Strength
- Static and Dynamic Compression-Shear Strength
- Torsional Strength
- Dynamic Construct Fatigue with Subsequent Fretting-Corrosion Analysis
- Nitinol Corrosion Test
- Wear Particle Analysis

I. Clinical Performance Evaluation

restor3d completed a retrospective, single arm, clinical evaluation of the TIDAL Fusion Cage using an intramedullary (IM) nail for tibiotalocalcaneal (TTC) fusion. Clinical performance was evaluated against an IM nail for TTC fusion. Effectiveness endpoints included joint salvage with the TIDAL Fusion Cage in place at last follow-up, perceived, physical function, and deformity correction. Safety outcomes included absence of a subsequent secondary surgical intervention and device-related serious adverse events on the affected joints.

J. Conclusions:

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Based on the data submitted, any differences of the TIDAL Fusion Cage System do not raise any different questions of safety or effectiveness, therefore, demonstrates substantial equivalence to the predicate device.