June 17, 2022

restor3d
Shyam Patel
Product Manager - Spine
404 Hunt St. Suite 500
Durham, North Carolina 27701

Re: K220523
Trade/Device Name: restor3d TiDAL Lumbar Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 16, 2022
Received: May 19, 2022

Dear Shyam Patel:

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,

Brent L. Showalter, Ph.D.
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)*
K220523

Device Name
restor3d TiDAL Lumbar Interbody Fusion Device

Indications for Use *(Describe)*

The restor3d lumbar cages are intended to be used as an intervertebral body fusion device with bone graft for use in lumbar spine. They are indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels from L2-S1. DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants are used to facilitate fusion in the lumbar spine using autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbar spine.

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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6. 510(k) Summary

Date Prepared: February 18, 2022

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:

Shyam Patel
Product Manager - Spine
shyam@restor3d.com

C. Premarket Notification:

Trade Name:	restor3d TiDAL Lumbar Interbody Fusion System
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device, Lumbar
Regulation Number:	21 CFR 888.3080
Product Code:	MAX
Classification:	II

D. Indications for Use:

The restor3d lumbar cages are intended to be used as an intervertebral body fusion device with bone graft for use in lumbar spine. They are indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels from L2-S1. DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Implants are used to facilitate fusion in the lumbar spine using autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device. The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbar spine.

E. Predicate Devices:

restor3d TiDAL Lumbar Interbody Fusion System is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K201755 K210583	Waveform (L, TO, TA, A) Interbody System	Seaspine
Additional Predicate Device		
K162496 K180556 K183239	F3d Interbody System	Corelink
K170851 K153436 K143258	Anterior Spine Truss System Interbody Fusion Device	4web

F. Device Description:

The restor3d TiDAL Lumbar Interbody Fusion System are additively manufactured Titanium Alloy (Ti-6AL-4V per ASTM F2924) implants, designed for use as a lumbar interbody fusion device. They are provided sterile-packed. The system is comprised of various sizes to accommodate individual patient anatomy as well as multiple designs to support several surgical techniques (PLIF, ALIF, TLIF, OLIF, LLIF). Each approach includes several offerings that vary by footprint (width and depth/length), height, and lordotic angle. All sizes have a large central window(s) for packing autogenous bone graft and/or allogenic bone graft. The inferior and superior faces have endplate surface lattices as well as teeth to resist migration when placed in between the vertebral bodies.

G. Technological Characteristics:

As was established in this submission, the restor3d TiDAL Lumbar Interbody Fusion System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, implant materials, product features, mechanical performance, and function.

H. Performance Testing:

Mechanical Performance testing was performed through compression and compression-shear (ASTM F2077), subsidence testing (ASTM F2267), and expulsion testing. In all,

the restor3d TiDAL Lumbar Interbody Fusion System has demonstrated mechanical performance equivalence and is substantially equivalent to the predicate devices.

I. Conclusions:

The restor3d TiDAL Lumbar Interbody Fusion System was shown to be substantially equivalent in performance and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, implant materials, product features, mechanical performance, and function. Based on the data submitted, the restor3d TiDAL Lumbar Interbody Fusion System does not raise any new questions about safety or effectiveness, therefore, demonstrates substantial equivalence to the predicate devices.