



January 22, 2024

restor3d  
Anika Moorjani  
Regulatory Engineer  
4001 E. NC 54 Highway, Suite 3160  
Durham, North Carolina 27709

Re: K234087

Trade/Device Name: restor3d TiDAL Lumbar Interbody Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: December 22, 2023  
Received: December 22, 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 (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.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -

S

for

Brent 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

## Indications for Use

510(k) Number (if known)  
K234087

Device Name  
restor3d TIDAL Lumbar Interbody Fusion System

### 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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## **510(k) Summary**

Date Prepared: January 18th, 2024

In accordance with the requirements of 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the restor3d TiDAL Lumbar Interbody Fusion System.

### **A. 510(k) Sponsor:**

restor3d, inc.  
4001 E. NC 54 Highway, Suite 3160  
Durham, North Carolina, 27709

### **B. Primary Correspondent:**

Anika Moorjani  
*Regulatory Engineer*  
(501) 240-3476 (direct)  
[anika@restor3d.com](mailto:anika@restor3d.com)

### **C. Premarket Notification:**

Trade Name: restor3d TiDAL Lumbar Interbody Fusion System  
Common Name: Lumbar Interbody Fusion Device  
Classification Name: Intervertebral Fusion Device With Bone Graft, Lumbar  
Regulation Number: 21 CFR 888.3080  
Product Code: MAX  
Classification: II  
Review Panel: Orthopedic

### **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:**

The Lumbar Interbody Fusion System is substantially equivalent to the following device:

510(k)	Trade Name	Manufacturer
<b>Primary Predicate Device</b>		
K220523	restor3d TiDAL Lumbar Interbody Fusion Device	restor3d, Inc.

**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. Performance Testing:**

Cleaning per ISO 17664-1 (FDA recognition #14-578), AAMI TIR30, and ASTM F565 (FDA recognition #11-199), sterilization per ISO 17665-1 (FDA recognition #14-333), ISO 17665-3, AAMI TIR 12, ISO 11737-1 (FDA Recognition #14-577), ISO 11737-2 (FDA Recognition #14-540), and ASTM F565 (FDA recognition #11-199), and biocompatibility per ISO 10993-1 to establish substantial equivalence in comparison to the predicate device.

## **H. Substantial Equivalence Comparison:**

Substantial equivalence of the disc preparation instruments and sterilization tray to the predicate device is based on the following:

- The inclusion of the disc preparation instruments and sterilization tray do not impact the indications for use and intended use of the Lumbar Interbody Fusion Device.
- Changes to provide a sterilization tray with disc preparation instruments are not shown to raise any new questions of safety or effectiveness.

## **I. Conclusion:**

Based on the comparison of the intended use and indications for use, the subject TiDAL Lumbar Interbody Fusion System is substantially equivalent to the predicate TiDAL Lumbar Interbody Fusion System. The addition of the disc preparation instruments provided in the sterilization tray does not raise any additional questions of safety and effectiveness.