restor3d
Nathan Evans
Vice President of Technology and Strategy
311 W Corporation Street
Durham, North Carolina 27701

October 24, 2019

Re: K191812
Trade/Device Name: ADI Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 19, 2019
Received: September 20, 2019

Dear Mr. 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,

for
Ronald P. Jean, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191812

Device Name
ADI Cervical Interbody Fusion Device

Indications for Use *(Describe)*
The restor3d Cervical Interbody Fusion Device is indicated for use as an intervertebral body fusion device 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 level of the cervical spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the cervical spine (C3-C7) and are placed via an anterior approach using autogenous bone as graft material for the interior graft window. The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical 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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510k Summary - K191812

510(k) Number: K191812

Date Prepared: June 28, 2019

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

A. Submitter:
restor3d
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: ADI Cervical Interbody Fusion Device
Common Name: Cervical Intervertebral Fusion Device (Cervical Cage)

D. Classification: Intervertebral Body Fusion Device (Class II)
21 CFR 888.3080

E. Predicate Device(s):
Spinal Elements Crystal®, K073351

F. Physical Description:
The proposed ADI Cervical Interbody Fusion Device is a sterile, single use implant grade titanium alloy (Ti-6Al-4V) device, available in varied footprints and heights, designed for supplemental stabilization of the cervical spinal column in anterior cervical discectomy and fusion (ACDF) procedures. The device is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. The implant is intended to be used with cleared fixation devices such as an anterior cervical plate system. The ADI device is comprised of a single, continuous piece of titanium alloy fabricated via additive manufacturing. The ADI device has a porous structure throughout

the body of the implant, a circular window for the packing of graft material, a threaded hole for insertion, teeth on the surfaces of the perimeters to aid expulsion resistance, and side windows on the walls of the implant.

G. Indications for Use:

The restor3d Cervical Interbody Fusion Device is indicated for use as an intervertebral body fusion device 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 level of the cervical spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the cervical spine (C3-C7) and are placed via an anterior approach using autogenous bone as graft material for the interior graft window. The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

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

The ADI Cervical Interbody Fusion Device is substantially equivalent to the predicate device (Spinal Elements Crystal®, K073351) in intended use and important physical and performance specifications. Although it differs from the predicate in the device material, the devices have similar design / physical characteristics (i.e., similar footprints, graft windows for packaging of graft material, side windows, and "teeth" features on implant surface) and the same indications for use. The proposed ADI device was subjected to the following performance tests to support the assertion of substantial equivalence*:*

- Comparative functional performance testing per ASTM F2077-18, *Test Methods For Intervertebral Body Fusion Devices*;
  - Static compressive strength
  - Dynamic compressive strength
  - Static torsional strength
  - Dynamic compressive strength
- Comparative wear analysis following dynamic compression
- Comparative expulsion resistance
- Comparative subsidence testing per ASTM F2267-04, *Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression*

No new questions of safety or effectiveness were identified during device testing; therefore, the ADI Cervical Interbody Fusion Device is considered substantially equivalent to the predicate device.