DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 6, 2016

Amendia, Incorporated
Ms. Kristen Allen
Senior Regulatory Affairs Specialist
1755 West Oak Parkway
Marietta, Georgia 30062

Re: K151310
Trade/Device Name: Amendia Interbody Fusion Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 7, 2015
Received: December 8, 2015

Dear Ms. Allen:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151310

Device Name
Amendia Interbody Fusion Devices

Indications for Use *(Describe)*

The Amendia Lumbar Interbody Fusion Devices are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Amendia Lumbar Interbody Fusion Devices are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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.

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AMENDIA
creating balanced solutions

510(k) Summary

Amendia Interbody Fusion Devices

Submitter: Amendia, Inc.
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Contact Person: Kristen Allen
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kallen@amendia.com (e-mail)

Date Prepared: January 5, 2016

Trade Name: Amendia Interbody Fusion Devices

Common Name: Intervertebral body fusion device

Device Product Code and Classification: MAX, 888.3080, Class II, Intervertebral Fusion Device with Bone Graft, Lumbar

Primary Predicate Device: Zeus Intervertebral Fusion Devices (K081614)

Additional Predicate Devices:
Nuvasive CoRoent System (K141665, K151472)
Amendia IBFD (K151322)
Medtronic Perimeter Interbody Fusion Device (K132700)
Biomet Lateral Spacer System (K122989)
Custom Spine Pathway (K080281)

Purpose of Submission: This 510(k) is intended to add additional LLIF (lateral) and OLLIF (oblique) implant models to the family of lumbar implants originally cleared in K081614.

Device Description:
The Amendia Interbody Fusion Devices are used to provide structural stability and maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The Subject Amendia Interbody Fusion Devices (LLIF and OLLIF) are multiple component systems comprised of sterile, single-use implants, designed to treat the lumbar spine.

The Subject Amendia Interbody Fusion System lumbar (LLIF and OLLIF) implants are fabricated from PEEK (ASTM F2026) with tantalum (ASTM F560) x-ray markers, or Titanium alloy (Ti6Al4V ELI, ASTM F136). The Amendia Interbody Fusion System implants are available in a range of sizes and shapes, and are designed to accommodate variations in surgical approach and patient anatomy. Each cage has a hollow center to allow placement of autograft. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

Indications and Intended use:

The Amendia Lumbar Interbody Fusion Devices are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Amendia Lumbar Interbody Fusion Devices are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Summary of Technological Characteristics:
The subject devices are substantially equivalent to the predicate devices as well as other similar devices cleared by FDA for commercial distribution in the United States. The Subject Device was shown to have the same technological characteristics as its predicate devices through comparison of characteristics including design, intended use, material composition, and function. Both the subject and predicate lumbar devices are interbody devices designed to contain graft material and facilitate fusion between two vertebral bodies in the lumbar region of the spine.

Summary of Performance Testing:
Non-clinical mechanical testing for the Subject Device was performed on the worst case subject device. Testing included static and dynamic axial compression and compression shear (ASTM F2077), subsidence (ASTM F2267), and expulsion testing. Performance testing demonstrated the Subject Device is substantially equivalent to the predicate device.

Conclusion:
Based on the comparison to predicate devices, the Subject Device has been shown to be substantially equivalent to legally marketed predicate devices.