



Food and Drug Administration
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November 8, 2016

Amendia, Inc.
Chelsea Proffitt
Regulatory Affairs Specialist
1755 West Oak Parkway
Marietta, Georgia 30062

Re: K160924

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, ODP
Dated: October 12, 2016
Received: October 13, 2016

Dear Chelsea Proffitt:

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 Part 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" (21 CFR 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160924

K160924

Page 1 of 1

Device Name

Amendia Interbody Fusion Devices

Indications for Use (Describe)

The Amendia Cervical Interbody Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Amendia Cervical Interbody Fusion Devices are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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 autograft and/or allograft comprised of cancellous and/or corticocancellous 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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510(k) Summary**Amendia Interbody Fusion Devices**

Submitter: Amendia, Inc.
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Contact Person: Chelsea Proffitt
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Date Prepared: November 4, 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

ODP, 888.3080, Class II, Intervertebral Fusion Device with Bone Graft, Cervical

Predicate Device: Amendia Interbody Fusion Devices (K151322)

Additional Predicate Devices: Amendia Interbody Fusion Devices (K151310)
Talos Intervertebral Body Fusion Devices, Talos-C
Cervical Intervertebral Body Fusion Device, Talos-C
(HA) Cervical Intervertebral Body Fusion Devices
(K150788)

Device Description:

The Amendia Interbody Fusion Devices consist of multiple components comprised of sterile and/or non-sterile, single-use implants fabricated from Titanium alloy (Ti6Al4V ELI, ASTM F136) or Invibio PEEK-Optima® LT1 or Solvay Advanced Polymers Zeniva™ ZA-500 PEEK (ASTM F2026) with tantalum (ASTM F560) x-ray markers. 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 Amendia Interbody Fusion Devices are comprised of implants designed to treat the cervical and lumbar spine. The implants are available in a range of sizes and shapes to accommodate variations in surgical approach and patient anatomy. Each cage has a hollow center to allow placement of autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion. The surface of the ridges on the titanium implants are roughened.

Indications and Intended use:

The Amendia Cervical Interbody Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Amendia Cervical Interbody Fusion Devices are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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 autograft and/or allograft comprised of cancellous and/or corticocancellous 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 device is 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 is equivalent to the predicates in regards to technological characteristics including design, intended use, material composition, and function.

Summary of Performance Testing:

The substantial equivalence of the Amendia Lumbar Interbody Fusion Devices to the predicate is shown by similarity in intended use, indications for use, materials, performance and fundamental scientific technology.

Conclusion:

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