DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2015

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

Re: K152460
Trade/Device Name: Rectangular Corpectomy Cage
Regulation Number: 21 CFR 888.3060
Regulation Name: Spine intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 22, 2015
Received: September 23, 2015

Dear Ms. 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,

Casey Hanley -S

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)*

K152460

K152460

Device Name
Rectangular Corpectomy Cage

Indications for Use *(Describe)*

The Rectangular Corpectomy Cage is a vertebral body replacement system indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The Rectangular Corpectomy Cage is intended for use with supplemental fixation cleared for use in the thoracolumbar spine and is to be used with autograft and/or allograft.

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

Rectangular Corpectomy Cage

Submitter: Amendia, Inc.
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Contact Person: Chelsea Proffitt
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Date Prepared: December 11, 2015

Trade Name: Rectangular Corpectomy Cage

Common Name: Spinal intervertebral body fixation orthosis

Device Product Code and Classification: MQP, 888.3060, Class II, Spinal Vertebral Body Replacement Device

Primary Predicate Device: Samson Corpectomy Cage (K091426)

Additional Predicate Devices: Synthes XRL System (K103320)
Phenix™ VBR (K072029)

Purpose of Submission: This traditional 510(k) is seeking clearance for modifications to the Samson Corpectomy Cage, including modifications to the shape, to add Ti6Al4V ELI implant configurations in addition to two PEEK materials (Invibio Optima LT1 and Solvay Zeniva ZA-500) and an addition of dimensions.

Device Description:

The Rectangular Corpectomy Cage consists of multiple components comprised of sterile, single-use implants fabricated from PEEK (ASTM F2026) with tantalum (ASTM F560) x-ray markers, or Titanium alloy (Ti6Al4V ELI, ASTM F136). The Rectangular Corpectomy Cage is used to replace a collapsed, damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures due to tumor or trauma. They are designed to be used in conjunction with supplemental spinal fixation instrumentation.

The Rectangular Corpectomy Cage is comprised of implants designed to treat the thoracolumbar spine. The implants are available in a range of sizes and shapes to accommodate anterior, anterolateral, lateral and posterolateral surgical approaches and patient anatomy. Each cage has a hollow center to allow placement of autograft and/or allograft. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

Indications and Intended use:
The Rectangular Corpectomy Cage is a vertebral body replacement system indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The Rectangular Corpectomy Cage is intended for use with supplemental fixation cleared for use in the thoracolumbar spine and is to be used with autograft and/or allograft.

Summary of Technological Characteristics:
The subject Rectangular Corpectomy Cage is substantially equivalent to predicate devices cleared 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 devices are vertebral body replacement devices designed to contain graft material and replace a collapsed, damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures due to tumor or trauma in the thoracolumbar region of the spine.

Summary of Performance Testing:
The substantial equivalence of the Rectangular Corpectomy Cage to the predicate is shown by similarity in intended use, indications for use, materials and performance. Non-clinical mechanical testing for the Rectangular Corpectomy Cage system was performed on the worst case subject device. Performance testing included static and dynamic compression (per ASTM F2077), static and dynamic torsion (per ASTM F2077) and expulsion testing. Design verification demonstrated the Subject Device is substantially equivalent to the predicate device.

Conclusion:
Based on the comparison to predicate devices and performance testing, the Rectangular Corpectomy Cage has been shown to be substantially equivalent to legally marketed predicate devices.