DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

January 14, 2016

Re: K152972
Trade/Device Name: Amendia Stand-Alone Cervical System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: December 17, 2015
Received: December 21, 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,

Mark N. Melkerson -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)*

K152972

K152972

Device Name
Amendia Stand-Alone Cervical System

Indications for Use *(Describe)*

The Amendia Stand-Alone Cervical System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Amendia Stand-Alone Cervical implant should be packed with autogenous bone graft and implanted with an anterior approach.

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 Stand-Alone Cervical System

Submitter: Amendia, Inc.
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Contact Person: Kristen Allen
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Date Prepared: January 13, 2016

Trade Name: Amendia Stand-Alone Cervical System

Common Name: Intervertebral Body Fusion Device with Integrated Fixation, Cervical

Device Product Code and Classification: OVE, Class II (§888.3080)

Primary Predicate: Zavation Z-Link Cervical System (K141005)

Device Description:
The Amendia Stand-Alone Cervical System includes a PEEK spacer component (medical grade Zeniva ZA-500, ASTM F2026) with Tantalum markers (ASTM F560), and a titanium interbody plate and screws (ASTM F136). The spacer component is assembled to the interbody plate and implanted anteriorly. The endplate contacting surfaces of the spacer component include serrations, and the plate component includes two holes for inserting one bone screw in each vertebral body. The plate component also includes a screw lock at each hole. The bone screws are available in a variety of diameters and lengths. The interbody plate components are available in a variety of heights. The spacer components are available in a variety of depths, widths, and heights.

Indications and Intended use:
The Amendia Stand-Alone Cervical System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Amendia Stand-Alone Cervical implant should be packed with autogenous bone graft and implanted with an anterior approach.

Summary of Technological Characteristics:
The Amendia Stand-Alone Cervical System is substantially equivalent to predicate devices cleared by FDA for commercial distribution in the United States. The Subject Device was shown to be identical to the predicate device in terms of design, intended use, performance specifications, material specifications, and technological characteristics.

Summary of Performance Testing:
Performance testing was not necessary since the Subject and Predicate Devices are identical with regards to intended use, indications for use, materials, manufacturing processes, and performance specifications.

Conclusion:
Based on the comparison to predicate device, the Amendia Stand-Alone Cervical System has been shown to be substantially equivalent to the legally marketed predicate device.