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

October 15, 2015

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

Re: K152455
Trade/Device Name: Amendia Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 27, 2015
Received: August 28, 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 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

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)* K152455

K152455

Device Name
Amendia Cervical Plate System

Indications for Use *(Describe)*

The Amendia Cervical Plate System is intended for use in anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), spinal stenosis, deformity (i.e. kyphosis, lordosis or scoliosis), tumor, pseudoarthosis or failed previous fusion.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Amendia Cervical Plate System

Submitter: Amendia, Inc.
1755 W. Oak Parkway
Marietta, GA 30062

Contact Person: Kristen Allen
Sr. Regulatory Affairs Specialist
910-612-4153 (P), 877-420-1213 (F)
kallen@amendia.com (e-mail)

Date Prepared: August 27, 2015

Trade Name: Amendia Cervical Plate System

Common Name: Spinal Intervertebral body fixation orthosis

Device Product Code and Classification: KWQ, Class II (§888.3060)

Primary Predicate: Zavation Cervical Plate System (K130030)

Device Description:
The Amendia Cervical Plate System is a multiple component system comprised of non-sterile, single-use implantable components fabricated from Titanium alloy (Ti-6Al-4V, ASTM F136). The Amendia Cervical Plate System provides stabilization of cervical segments of the spine. The system consists of self-tapping/self-drilling screws and plates. Screws are available in a variety of diameter and length combinations. Plates are available in a variety of lengths.

Indications and Intended use:

The Amendia Cervical Plate System is intended for use in anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), spinal stenosis, deformity (i.e. kyphosis, lordosis or scoliosis), tumor, pseudoarthosis or failed previous fusion.

Summary of Technological Characteristics:
The Amendia Cervical Plate 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:
The substantial equivalence of the Subject Device to the predicate is shown by both having the same intended use, indications for use, materials, and performance specifications. A risk analysis

was performed, which demonstrated that the subject device does not introduce new issues of safety or effectiveness.

Conclusion:
Based on the comparison to predicate devices and performance testing, the Amendia Cervical Plate System has been shown to be substantially equivalent to the legally marketed predicate device.