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

April 27, 2016

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

Re: K153152
Trade/Device Name: Syzygy Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: March 24, 2016
Received: March 25, 2016

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)*

K153152

Device Name
Syzygy Stabilization System

Indications for Use *(Describe)*

The Syzygy Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine, specifically as follows:

• When intended for pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients the Syzygy Stabilization System is indicated for one or more of the following: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and/or failed previous fusion (pseudarthrosis).

• In addition, when used as a pedicle screw fixation system, the Syzygy Stabilization System is indicated for skeletally mature patients having degenerative spondylolisthesis with objective evidence of neurologic impairment and/or severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and who are having the device removed after the development of a solid fusion mass.

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

Syzygy Stabilization 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:	April 26, 2016
Trade Name:	Syzygy Stabilization System
Common Name:	Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
Device Product Code and Classification:	Regulation Number: 21 CFR 888.3070 **NKB**, Class III, Pedicle Screw Spinal System, For Degenerative Disc Disease **MNI**, Class II, Pedicle Screw Spinal System **MNH**, Class II, Spondylolisthesis Spinal Fixation Device System
Primary Predicate:	Savannah Lumbar Percutaneous Stabilization System (K072116)
Additional Predicate:	Savannah-T Pedicle Screw System (K132925) Pangea (K052123) Talon Spinal System (K102995)

Device Description:
The Syzygy Stabilization System consists of posted screws, couplers, and associated surgical instruments. The system is used in conjunction with the Amendia Savannah-T pedicle screw and rod system. The Syzygy posted screws are self-tapping with a cancellous thread design. They are available in cannulated and non-cannulated configurations, in a variety of diameters and lengths. The Syzygy posted screws are attached to the pedicles via couplers (medial and cranial) which accept and secure the longitudinal rods to build a rigid construct. The screws and couplers are manufactured from Ti-6Al-4V (ASTM F136) and are provided non-sterile for single-use.

Indications and Intended use:
The Syzygy Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine, specifically as follows:

- When intended for pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients the Syzygy Stabilization System is indicated for one or more of the following: degenerative disc disease (defined as discogenic back pain with degeneration of

the disc confirmed by history and radiographic studies); spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and/or failed previous fusion (pseudarthrosis).

- In addition, when used as a pedicle screw fixation system, the Syzygy Stabilization System is indicated for skeletally mature patients having degenerative spondylolisthesis with objective evidence of neurologic impairment and/or severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and who are having the device removed after the development of a solid fusion mass.

Summary of Technological Characteristics:
The subject device is substantially equivalent to the predicate device as well as other similar devices cleared by FDA for commercial distribution in the United States. The Subject Device is equivalent to the predicate in regards to technological characteristics including design (rod, screw and coupler configuration), intended use (as described above), material composition (Titanium Alloy), sizes (dimensions are comparable to those offered by the predicate systems) and fundamental scientific technology (same as previously cleared devices).

Summary of Performance Testing:
Mechanical testing for the Syzygy Stabilization System was performed on the worst case subject device in accordance with ASTM standards.

Test	Standard
Static Axial Compression Bending	ASTM F1717-14
Static Axial Tension Bending	ASTM F1717-14
Static Torsion	ASTM F1717-14
Dynamic Axial Compression Bending	ASTM F1717-14
Dynamic Axial Tension Bending	ASTM F1717-14

A cadaveric validation study was also performed.

For all test methods, the subject devices met the requirements as established by the test protocol and applicable ASTM standards. The results demonstrated that the Subject device is substantially equivalent to the Predicate.

Conclusion:
Based on the comparison to predicate device, the Syzygy Stabilization System has been shown to be substantially equivalent to the legally marketed predicate device.