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

July 8, 2016

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

Re: K152920
Trade/Device Name: Savannah-T® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: June 17, 2016
Received: June 20, 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)*
K152920

Device Name
Savannah-T® Pedicle Screw System

Indications for Use *(Describe)*
The Savannah-T® Pedicle Screw 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 Savannah-T® 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 Savannah-T® 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.

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510(k) Summary

Savannah-T® Pedicle Screw System

Submitter: Amendia, Inc.
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Marietta, GA 30062

Contact Person: Kristen Allen
Sr. Regulatory Affairs Specialist
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kallen@amendia.com (e-mail)

Date Prepared: June 17, 2016

Trade Name: Savannah-T® Pedicle Screw System

Common Name: Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease

Device Product Code and Classification:
Regulation Number: 21 CFR 888.3070
MNH, Class II, Spondylolisthesis Spinal Fixation Device System
MNI, Class II, Pedicle Screw Spinal System
NKB, Class III, Pedicle Screw Spinal System, For Degenerative Disc Disease

Primary Predicate Device: Savannah-T® Pedicle Screw System (K132925)

Additional Predicate: Talon Spinal System (K102995)

Purpose of Submission: This special 510(k) is intended to gain clearance for addition of pre-contoured fixation rods to the Savannah-T® Pedicle Screw System.

Device Description:
The Savannah-T® Pedicle Screw System provides structural stability in skeletally mature adults requiring fusion of the lumbar and/or sacral spine. The system consists of mono- and poly-axial pedicle screws, connecting rods, set screws, and transverse crossmembers. The screws are available in cancellous and cortical-cancellous thread designs of various diameters and lengths. The rods are available in straight, lordosed and pre-contoured configurations in various lengths. They are manufactured from Ti-6Al-4V (ASTM F136) and are provided non-sterile for single-use.

Indications and Intended use:

The Savannah-T® Pedicle Screw 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 Savannah-T® 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 Savannah-T® 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 devices are 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 identical to the predicate in regards to technological characteristics including design, intended use, material composition, and function.

Summary of Performance Testing:
Non-clinical mechanical testing for the Subject Device was performed on the worst case subject device. Testing included static/dynamic axial compression and static torsion (ASTM F1717), as well as secondary bending testing (dynamic compression, ASTM F1717). Performance testing demonstrated the Subject Device is substantially equivalent to the predicate device.

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