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

October 13, 2016

Re: K161842
Trade/Device Name: Overwatch Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP
Dated: September 9, 2016
Received: September 12, 2016

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 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" (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,

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)*

K161842

Device Name
Overwatch Spine System

Indications for Use *(Describe)*

The Overwatch Spine System is intended for non-cervical pedicle and non-pedical fixation (T1-S2/Ilium) in skeletally mature patients as an adjunct to fusion for the following instabilities/deformities in the thoracolumbar and sacral spine:

a) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
b) spondylolisthesis,
c) trauma (i.e., fracture or dislocation),
d) spinal stenosis,
e) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
f) tumor,
g) pseudoarthrosis, and
h) failed previous fusion

The Overwatch Spine System is intended for the following indications when used in a posterior percutaneous approach for non-cervical pedicle and non-pedical fixation: Degenerative disc disease; spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients the Overwatch Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior 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

Overwatch Spine System

Submitter: Amendia, Inc.
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Contact Person: Chelsea Proffitt
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Date Prepared: September 9, 2016

Trade Name: Overwatch Spine System

Common Name: Spinal Fixation System

Device Product Code and Classification: Regulation Numbers: 21 CFR 888.3070
21 CFR 888.3050

NKB, Class III, Pedicle Screw Spinal System, For Degenerative Disc Disease
OSH, Class II, Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis
MNH, Class II, Spondylolisthesis Spinal Fixation Device
MNI, Class II, Pedicle Screw Spinal System
KWP, Class II, Spinal Interlaminal Fixation Orthosis

Primary Predicate Device: Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K151488)

Additional Predicate Devices: CD HORIZON Spinal System (K153589)
Savannah-T Pedicle Screw System (K132925)

Device Description:
The Overwatch Spine System consists of spinal implants for fixation of the thoracolumbar and/or sacral spine. The system includes rods, screws, set screws, transverse crosslinks, rod connectors, and hooks. The Overwatch screws are self-tapping and are available with either a cancellous or a dualfix thread design. They are available in cannulated and non-cannulated configurations, in a variety of diameters and lengths. The system implants are manufactured from Ti-6Al-4V (ASTM F136).

Indications and Intended use:
The Overwatch Spine System is intended for non-cervical pedicle and non-pedical fixation (T1-S2/Ilium) in skeletally mature patients as an adjunct to fusion for the following instabilities/deformities in the thoracolumbar and sacral spine:

a) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)

b) spondylolisthesis,

c) trauma (i.e., fracture or dislocation),

d) spinal stenosis,

e) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),

f) tumor,

g) pseudoarthrosis, and

h) failed previous fusion

The Overwatch Spine System is intended for the following indications when used in a posterior percutaneous approach for non-cervical pedicle and non-pedical fixation: Degenerative disc disease; spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients the Overwatch Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Summary of Technological Characteristics:
The subject device is substantially equivalent to the predicate devices as well as other similar devices cleared by FDA for commercial distribution in the United States. The Subject Device is equivalent to the predicates in regards to technological characteristics including design, intended use, material composition, and function.

Summary of Performance Testing:

Mechanical testing for the Overwatch Spine System was performed on the worst-case subject device in accordance with ASTM standards.

Test	Standard
Static Axial Compression Bending	ASTM F1717-15
Static Torsion	ASTM F1717-15
Dynamic Axial Compression Bending	ASTM F1717-15
Axial Pullout	ASTM F543-13
Static Cantilever Screw Bending	ASTM F2193-14

For all test methods, the subject devices met or exceeded the requirements as established by the test protocol and applicable ASTM standards.

Performance testing of the Subject Device was compared to similar legally marketed Predicate and Reference Devices.

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