



Food and Drug Administration
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Silver Spring, MD 20993-0002

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

February 18, 2016

Re: K160291
Trade/Device Name: Optimus ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: February 1, 2016
Received: February 3, 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 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

Indications for Use

510(k) Number (if known)

K160291

Device Name

Optimus ALIF System

Indications for Use (Describe)

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient should be skeletally mature and have had six months of non-operative treatment.

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is a stand-alone system intended to be used with bone screws, autogenous bone graft and requires no additional supplementary fixations. One device is used per intervertebral space.

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
Optimus

K160291
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Date Prepared: February 7, 2016

Trade Name: Optimus ALIF System

Device Product Code and Classification: OVD, 888.3080, Class II, Intervertebral body fusion device

Primary Predicate Device: Optimus ALIF System (K132596)

Purpose of Submission: This special 510(k) is intended to gain clearance for a modification to the Optimus Stand-Alone ALIF System, specifically for the trial distractor instrument.

Device Description:

The Optimus Anterior Lumbar Interbody Fusion (ALIF) system is a zero profile stand-alone interbody that combines the benefits of an anterior fixation plate and fusion device. Optimus is a modular design that consists of a center fixation plate, lordotic end caps and three bone screws for anterior fixation and stability. The bone screws thread into the fixation plate and pass through the superior and inferior openings of the end caps to fixate the implant with the adjacent vertebral bodies.

OPTIMUS is available in a variety of heights (9-13mm posterior), angles (6 to 14 degrees) and two footprints to accommodate variations in patient anatomy. The fixation plates are manufactured from Titanium (ASTM F136), and the end caps are available in PEEK (ASTM F2026) and titanium (Ti-6Al-4V, ASTM F136), and are plasma sprayed with CP-titanium (ASTM F1580). The bone screws manufactured from Titanium (ASTM F136) are Ø5mm and are available in lengths from 24 to 32mm.

Indications and Intended use:

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at

the involved levels. The patient should be skeletally mature and have had six months of non-operative treatment.

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is a stand-alone system intended to be used with bone screws, autogenous bone graft and requires no additional supplementary fixations. One device is used per intervertebral space.

Summary of Technological Characteristics:

There are no changes being proposed for the Subject Device with respect to intended use, design, material composition, and function. The only change being proposed for the currently marketed device is a change in sterilization status for the Trial Distractor instrument (Class I).

Summary of Performance Testing:

Cleaning and steam sterilization validations were performed to verify method suitability.

Conclusion:

Based on comparison to the predicate device, the Subject Device has been shown to be substantially equivalent.