APR 11 2014

510(k) Summay

Date Prepared

April 11th, 2014

Name of Firm

Custom Spine, Incorporated
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Official Correspondent

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Establishment Number

3005129649

Device Name

Legally Marketed Trade Name: (Proposed) OPTIMUS
Common Name: Lumbar stand-alone intervertebral body fusion device
Device Classification: Class II
Regulation Number: 21 CFR 888.3080
Device Product Codes: OVD

Predicate Devices

Custom Spine's Pathway AVID (K111726, K090566), Orthofix's Pillar SA (K081849), Spinal USA Vault (K130445, K103369), Spinal Elements Lucent (K110632), X-Spine's Calix (K112036)

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. The device is available in two footprints, multiple heights, lordotic angles and screw lengths.

OPTIMUS: Device Characteristics	
Footprint L x W (mm)	25 x 32 29 x 36
Lordotic Angles (deg)	6, 10, 14
Heights (mm)	9-13 (Posterior)
Number of Bone Screws	3
Bone Screw Diameter (mm)	5.0
Bone Screw Lengths	24-32

Indications for Use

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures at one or two contiguous levels (L2-SI) 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.

Materials

The following materials are used in the Optimus system:

- Fixation Plates are manufactured from titanium (Ti-6Al-4V, ASTM F136)
- End Caps are manufactured from PEEK Optima LT1 (Polyetheretherketone, ASTM F2026) and titanium (Ti-6Al-4V, ASTM F136) and are coated with plasma sprayed CP-titanium (ASTM F1580)
- Bone Screws are manufactured from titanium (Ti-6Al-4V, ASTM F136)

Performance Data

Testing was performed in accordance to the following standards:

- Static Compression as per **ASTM F2077**
- Static Compression Shear as per **ASTM F2077**
- Static Torsion as per **ASTM F2077**
- Dynamic Compression as per **ASTM 2077**
- Dynamic Compression Shear as per **ASTM 2077**
- Subsidence as per **ASTM F2267**
- **Expulsion as per ASTM F04.25.02.02 (Draft standard)**

The Optimus device demonstrated to be mechanically superior in static compression, static shear, and static torsion, compared to the previously cleared predicate devices (Pillar SA and Pathway AVID). Additionally, the Optimus device demonstrated to be mechanically equivalent in subsidence and expulsion, compared to the previously cleared predicate devices (Pillar SA and Pathway AVID)

Substantial Equivalence Statement

Documentation is provided to demonstrate that the OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is substantially equivalent to its predicate devices in terms of its material, design, indications for use, and performance characteristics.

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 11, 2014

Custom Spine, Incorporated
Ms. Hanaa Shahin
Regulatory Affairs and Quality Assurance
9 Campus Drive
Parsippany, New Jersey 07054

Re: K132596
Trade/Device Name: OPTIMUS
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 6, 2014
Received: March 10, 2014

Dear Ms. Shahin:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section VI. INDICATIONS FOR USE STATEMENT

510(K) NUMBER: K132596

DEVICE NAME: OPTIMUS

Intended Use/Indications for Use

The OPTIMUS Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures at one or two contiguous levels (L2-SI) 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.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices