Southern Spine LLC
Traditional 510(k) - C·Fuse™ Cervical Intervertebral Body Fusion System

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Southern Spine LLC
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Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

AUG 14 2013

Date Submitted: Revised - August 5, 2013

Device Name and Classification:

Trade/Proprietary Name:	C·Fuse™ Cervical Intervertebral Body Fusion System
Common Name:	Cervical Intervertebral Body Fusion System
Classification Name:	Intervertebral body fusion device
Product Code:	ODP
Regulation:	21 CFR 888.3080
Class:	2

Legally Marketed Predicate Device:

Spinal Devices, LLC [Current Name is Amendia, Inc.] - Phenix Cervical Interbody Device (Phenix® CID) - 510(k) # K083167

Lanx, Inc. - Lanx Fusion System (Includes Breckenridge Interbody/VBR Fusion System) – 510(k) # K103660

Device Description:

The C·Fuse Cervical Intervertebral Body Fusion System is a cervical interbody fusion device designed to be inserted within the intervertebral disc space in order to provide structural stability and act as an adjunct to spinal fixation. The device is trapezoidal in shape, with machined grooves on the superior and inferior surfaces, along with a hollow center core to accept autogenous bone graft. There are two materials used in the manufacture of the Southern Spine C·Fuse Cervical Intervertebral Body Fusion System devices which are the Zeniva® ZA-500 (PEEK) under ASTM F2026 and Tantalum Wire Type R05400 under ASTM F560. There is instrumentation for implantation and a sterilization tray for steam sterilization. The implants are non-sterile and single use. The instrumentation is non-sterile and reusable.

Indications for Use:

The Southern Spine C·Fuse™ Cervical Intervertebral Body Fusion System is intended for single level spinal fusion procedures in skeletally mature patients with degenerative disc disease ("DDD") of the cervical spine. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The C·Fuse device is to be implanted via an anterior approach at the C3 to C7 disk levels using autogenous bone graft and is to be combined with supplemental fixation. Patients should have had at least six weeks of non-operative treatment prior to treatment with the device.

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Similarities and Differences to the Predicate Devices:

Similarities

The same materials, the same performance standards, and the same indications for use are used in the C·Fuse™ Cervical Intervertebral Body Fusion System and the predicate devices. The C·Fuse and predicate devices include approximately the same size ranges for use in cervical C-3 to C-7 disc levels. The devices all have a hollow center core to accept autogenous bone graft. The C·Fuse and predicate devices provide instrumentation sets and sterilization trays as accessories for use during implantation.

Differences

The PEEK resin and tantalum materials are from different manufacturers than the predicates; however, no issue with biocompatibility was shown with the C·Fuse device. The C·Fuse and the predicate devices have roughly the same device dimensions and characteristics.

Summary of Testing:

The C·Fuse Cervical Intervertebral Body Fusion System was tested to the ASTM F2077 and ASTM F2267 standards as identified in "Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", Dated June 12, 2007 as appropriate for characterization of intervertebral body fusion devices. Testing included static axial and compression shear testing, dynamic axial and compression shear testing, static and dynamic torsion testing, static subsidence testing, and static expulsion testing.

Substantial Equivalence Conclusions:

The C·Fuse Cervical Intervertebral Body Fusion System has the same intended use and fundamental scientific technology as the predicate devices. The minor differences do not raise any issues of safety or effectiveness. Testing results support the determination of substantial equivalence for the C·Fuse Cervical Intervertebral Body Fusion System against the predicate devices.

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

August 14, 2013

Southern Spine, LLC
% Regulatory Resources Group, Incorporated
Ms. Julie Stephens
President/Consultant
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K130948
Trade/Device Name: C·Fuse™ Cervical Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 28, 2013
Received: June 28, 2013

Dear Ms. Stephens:

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,

For Erin I. Keith

Mark 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): K130948

Device Name: C·Fuse™ Cervical Intervertebral Body Fusion System

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices