510(k) Summary
Cervical Intervertebral Body Fusion System

510(k) Number K122771

JAN 10 2013

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
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Contact Information:
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Date Prepared: January 9, 2013

Proprietary Name	Cervical Intervertebral Body Fusion System
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Intervertebral Body Fusion Device)
Proposed Regulatory Class	Class II
Device Product Code	OVE

Purpose of this Special 510(k)
This 510(k) seeks clearance for a new system.

Device Description
Spinal Elements' Cervical Intervertebral Body Fusion System is composed of an implant body and fixation screws. The implant body is a generally box-shaped device with holes through its body for the placement of graft material. Additionally, it has teeth located on its superior and inferior external surfaces to help keep the device from migrating once placed in its desired location. There are also screw holes located in the implant body. Each screw hole is lined in its internal surface with a titanium ring insert.

Screws pass through screw holes of the implant body and affix to bone to help prevent implant migration. When fully seated, the screw head rests on the titanium insert of the screw hole.

Device implant bodies are made from either titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3 or polyetheretherketone conforming to ASTM F 2026.

Screws are made from Ti-6Al-4V per ASTM F 136 or ISO 5832-3 with certain subcomponents manufactured from nitinol conforming to ASTM F2063.

Intended Use of the Device

The Spinal Elements Cervical Intervertebral Body Fusion System is a stand-alone interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

Performance Data

Non-clinical, mechanical testing was performed to determine the performance profile of the device. Testing included:

- Static Compression testing as per ASTM F 2077-03
- Static Torsion testing as per ASTM F 2077-03
- Dynamic Compression testing as per ASTM F 2077-03
- Dynamic Torsion testing as per ASTM F 2077-03
- Subsidence Testing as per ASTM F 2267-04

All test results indicate the device will perform as intended based on a comparison to devices cleared for similar or identical indications for use.

Substantial Equivalence

The device seeking clearance is substantially equivalent to the Spinal Elements Mosaic system cleared under K071833, and the Globus Coalition system cleared under K083389. The indications for use, intended use, surgical technique, materials, and technological characteristics are virtually the same.

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

Spinal Elements, Incorporated
% Mr. Benjamin A. Kimball
Regulatory Affairs Manager
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Letter dated: January 10, 2013

Re: K122771
Trade/Device Name: Cervical Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: December 3, 2012
Received: December 10, 2012

Dear Mr. Kimball:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) K:122771

Device Name: Cervical Intervertebral Body Fusion System

Indications for Use:
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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)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122771