K120819

510(k) Summary

AUG 3 1 2012

Device Trade Name: STALIF C®

Manufacturer:
Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380

Contact:
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Development Manager
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Prepared by:
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Date Prepared: May 4, 2012

Classifications: 21 CFR 888.3080, Intervertebral body fusion device

Class: II

Product Codes: OVE

Indications For Use:
The STALIF C® is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF C® is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Device Description:
STALIF C® is a radiolucent intervertebral body fusion cage with unicortical cancellous bone screws. It is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF C® is similar to that of the vertebral body endplate with central cavity that can be packed with autograft. STALIF C® is manufactured from PEEK-OPTIMA®

LT1 with titanium alloy screws and X-ray marker wires manufactured from unalloyed Tantalum (ASTM F-560).

Predicate Device:
The subject STALIF C® intervertebral body fusion device is substantially equivalent to predicate STALIF C™ (K072415), Stryker Spine Anchor-C Cervical Cage System (K102606), Spinal Elements Mosaic Cage (K071833), and the Medtronic Affinity Cages (P000028), with respect to indications, design, function, and materials.

Substantial Equivalence:
FEA simulation was performed on the worst case subject STALIF C® and predicate STALIF C™ to show the previous testing in K072415 was adequate. Additional mechanical testing per ASTM F2077 (e.g., static and dynamic compression, static and dynamic compression-shear, and static and dynamic torsion testing) was performed on the worst-case device. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Centinel Spine, Incorporated
% Mr. John Parry
Development Manager
900 Airport Road, Suite 3B
West Chester, Pennsylvania 19380

AUG 3 1 2012

Re: K120819
Trade/Device Name: STALIF C®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: August 02, 2012
Received: August 06, 2012

Dear Mr. Parry:

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.

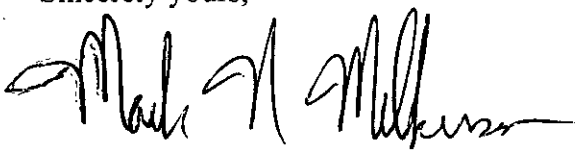
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K120819

Device Name: STALIF C®

The STALIF C® is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF C® is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Prescription Use ___√___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120819