



Food and Drug Administration
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Centinel Spine, Incorporated
% Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors, LLC.
1331 H Street, Northwest 12th Floor
Washington, District of Columbia 20005

June 8, 2015

Re: K150643

Trade/Device Name: Centinel Spine STALIF TTTM, STALIF MIDLINE[®], MIDLINE IITM,
and MIDLINE II-TiTM

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: OVD

Dated: March 11, 2015

Received: March 12, 2015

Dear Mr. Eggleton:

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" (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 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)
K150643

Device Name
Centinel Spine STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™

Indications for Use (Describe)

The STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ system must be used with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name: Centinel Spine STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™

Manufacturer: Centinel Spine, Inc.
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Date Prepared: June 4, 2015

Classifications: 21 CFR §888.3080, Intervertebral Body Fusion Device.

Class: II

Product Codes: OVD

Primary Predicate Device: K141942, (Centinel Spine MIDLINE II™, and MIDLINE II-Ti™)

Additional Predicate Devices: K101301, K073109 (Centinel Spine STALIF TT™, STALIF MIDLINE®)

Indications For Use:

The STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems.

The STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ system must be used with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

Device Description:

STALIF TT™, MIDLINE™/ MIDLINE II-Ti™ are radiolucent intervertebral body fusion cages 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 devices are similar to that of the vertebral body endplate with central cavity that can be packed with autograft or allograft. The STALIF devices are manufactured from PEEK-OPTIMA® LT1 with titanium alloy screws and X-ray marker wires manufactured from unalloyed Tantalum (ASTM F-560). The MIDLINE II-Ti™ is identical to this design with a titanium plasma spray coating on the device endplates.

The purpose of the subject 510(k) was to expand the indications to include use with allograft (i.e., allogenic bone graft composed of cancellous and/or corticocancellous bone graft).

Predicate Device (Summary of Technological Characteristics):

The subject STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ Interbody Fusion Device System is substantially equivalent to the predicate MIDLINE™/MIDLINE II-Ti™ Interbody Fusion Device System (K141942), STALIF MIDLINE® (K101301) and STALIF TT™ (K073109) with respect to indications, design, function, and materials.

Substantial Equivalence:

The subject and predicate STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ Device Systems are similar in design, material, and indicated use. A comprehensive, clinical literature review and PearlDiver reimbursement assessment were conducted to assess the safety and efficacy of allograft used in conjunction with this device in the lumbar spine. This review concluded that there were no additional risks due to the modified indications for this device. Biomechanical studies were performed to demonstrate equivalence to interbody cages with supplemental fixation. No new mechanical tests were performed since there were no design changes to the device.

Conclusion:

The Centinel Spine STALIF TT™, STALIF MIDLINE®, MIDLINE II™, and MIDLINE II-Ti™ have been modified to expand the indications to permit use with allograft (i.e., allogenic bone graft composed of cancellous and/or corticocancellous bone graft). The 510(k) demonstrates substantial equivalence to predicate devices.