DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Centinel Spine, Incorporated
Ms. Jessica Staub
Director, Quality and Regulatory
900 Airport Road, Suite 3B
West Chester, Pennsylvania 19380

December 1, 2015

Re: K152211
Trade/Device Name: Centinel Spine PCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: October 28, 2015
Received: October 30, 2015

Dear Ms. Staub:

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 Parts 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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152211

Device Name
Centinel Spine PCT System

Indications for Use *(Describe)*
The CENTINEL SPINE PCT SYSTEM is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CENTINEL SPINE PCT SYSTEM is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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4. 510(k) Summary

Device Trade Name: Centinel Spine PCT System

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

Contact:
Ms. Jessica Staub
Director, Quality and Regulatory
Phone: (484) 887.8803

Prepared by:
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Date Prepared: October 28, 2015

Classifications: Unclassified (Pre-Amendment Device)

Class: Unclassified

Product Codes: NKG, KWP

Primary Predicate: DePuy Synthes Spine Synapse System (K142838)

Additional Predicates:
Pioneer Surgical Technology Streamline OCT System (K121725)
Blackstone Posterior Cervical System (K030197)
Exactech Gibralt Spinal System (K140645, K110197)

Indications For Use:
The CENTINEL SPINE PCT SYSTEM is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The CENTINEL SPINE PCT SYSTEM is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

Summary of Technological Characteristics:
The Centinel Spine PCT System consists of a variety of shapes and sizes of rods, hooks, polyaxial screws, and connecting components (e.g., variable and fixed cross connectors). The hooks and polyaxial screws are intended to be attached to the posterior elements of the cervical and/or upper thoracic spine and serve as bone anchors. The rods are longitudinally secured to the bone anchors with the set screw. The various connecting components serve to both secure the construct and provide additional construct configuration options. All implants are manufactured from titanium alloy, Ti6Al4V (ASTM F136 or ISO 5832-3)

Predicate Device:
The subject Centinel Spine PCT System is substantially equivalent to the predicate devices cited in this 510(k) summary with respect to indications, design, function, and performance.

Substantial Equivalence:
Centinel Spine PCT System and the primary predicate DePuy Synthes Spine Synapse OCT system are similar in indications for use, design, material, function, and performance. Additional comparisons were made to alternate predicate devices with the same indications for use, design, material, function, and performance.

Performance Testing:
Published literature and performance testing indicates the Centinel Spine PCT System is as mechanically sound as predicate devices. Testing included static compression, static torsion, dynamic compression, and dynamic torsion per a modified version of ASTM F1717. ASTM F1798 testing included axial slip and torsional grip testing. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Conclusion:
The purpose of this 510(k) is to introduce the Centinel Spine PCT System to interstate commerce. The 510(k) demonstrates substantial equivalence to the predicate devices cited in this summary.