



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

September 3, 2015

Spinal Elements, Incorporated
Ms. Cecilia Silva
Regulatory Affairs Specialist
3115 Melrose Drive; Suite 200
Carlsbad, California 92010

Re: K151705

Trade/Device Name: Lotus[®] Posterior Cervical/Thoracic Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: August 24, 2015
Received: August 25, 2015

Dear Ms. Silva:

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" (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,

Lori A. Wiggins -S

for
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)

K151705

Device Name

Lotus® Posterior Cervical/Thoracic Spinal System

Indications for Use (Describe)

The Spinal Elements Lotus Posterior Cervical/Thoracic Spinal 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/thoracic 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 Lotus Posterior Cervical/Thoracic Spinal 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.

In order to achieve additional levels of fixation, the Lotus Posterior Cervical/Thoracic Spinal System may be connected to the Mercury® Spinal System with the Lotus Posterior Cervical/Thoracic rod connectors. Transition rods with differing diameters may also be used to connect the Lotus Posterior Cervical/Thoracic Spinal System to the Mercury Spinal System. Refer to the Mercury Spinal System package insert for a list of the Mercury Spinal System indications for use.

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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510(k) Summary
Lotus® Posterior Cervical/Thoracic Spinal System

510(k) Number K151705

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
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Carlsbad, CA 92010
760-607-0121

Contact Information: Cecilia Silva
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Date Prepared: August 24th, 2015

Proprietary Name : Lotus® Posterior Cervical/Thoracic Spinal System

**Regulatory Identification/
Classification:** Orthosis, Cervical Pedicle Screw Spinal Fixation
Product Code: NKG
Unclassified

Appliance, Fixation, Spinal Interlaminar
Product Code: KWP
21 CFR Section 888.3050
Class II

Purpose of this 510(k)

This 510(k) seeks clearance for expanded indications and line additions to the Lotus® Posterior Cervical/Thoracic Spinal System previously cleared for use under K120467 and K131427.

Device Description

The Lotus Posterior Cervical/Thoracic Spinal System consists of a variety of fixation devices manufactured from Ti-6Al-4V that are attached to the spine. Screws may be placed from a posterior approach into the cervical and/or thoracic spine. Hooks may be placed on the posterior elements of the various vertebrae. Rods span the distance between the screws/hooks, and various other connectors may be used between rods or between

Spinal Elements, Inc.
Premarket Notification – Lotus® Posterior Cervical/Thoracic Spinal System

rods and screws/hooks. The system achieves fixation by the mechanical joining of the rods, screws, hooks and connectors. A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient.

Indications for Use

The Spinal Elements Lotus Posterior Cervical/Thoracic Spinal 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/thoracic 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 Lotus Posterior Cervical/Thoracic Spinal 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.

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Substantial Equivalence

The subject Lotus devices are substantially equivalent in indications for use, surgical technique, design features and instrumentation to the following predicate devices:

Primary Predicate

- Medtronic's VERTEX® Reconstruction System (K143471)

Reference Devices

- Spinal Elements' Lotus Posterior Cervical/Thoracic Spinal System (K120467, K131427).

Performance Data

Published literature and performance testing support substantial equivalence. Tests included:

- Interconnection testing per ASTM F 1798
- Dynamic Compression Bending per ASTM F 1717

All data indicates that the device will perform as intended.