DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 2016

Spinal Elements, Incorporated
Julie Lamothe, Ph.D., MBA
Regulatory Affairs and Quality Assurance Director
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K160465
Trade/Device Name: Spinal Elements' Spinous Process Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: June 20, 2016
Received: June 22, 2016

Dear Dr. Lamothe:

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,

Vincent J. Devlin -S

for
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)*
K160465

Device Name
Spinal Elements' Spinous Process Plate System

Indications for Use *(Describe)*

Spinal Elements' Spinous Process Plate System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1) of skeletally mature patients. It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (i.e. fracture or dislocation), spondylolisthesis, and/or tumor. Spinal Elements' Spinous Process Plate System is not intended for stand-alone 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
Spinal Elements' Spinous Process Plate System

510(k) Number K160465

Manufacturer Identification
Submitted by: Spinal Elements Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
760-607-0121

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Date Prepared: July 7, 2016

Proprietary Name	Spinal Elements' Spinous Process Plate System
Common Name	Spinous Process Plate
Device Classification	21 CFR Section 888.3050
Classification Name	Spinal interlaminal fixation orthosis
Proposed Regulatory Class	Class II
Device Product Code	PEK

Purpose of this 510(k)
This Traditional 510(k) seeks clearance for a new spinal system. The new devices have an identical intended use and fundamental scientific technology as the predicate.

Device Description
Spinal Elements' Spinous Process Plate System is comprised of a static plate and a translating plate for posterior fixation of the spine in order to achieve fusion. The plates are available in multiple sizes to accommodate various patient anatomies. Both the static plate and the translating plate present spikes to interface with the bone of the spinous processes. The barrel of the static plate passes through the insert of the translating plate such that, in their final position, the plates surround the spinous processes on both sides, and fixation is achieved via compression of the two components onto the spinous processes. The spinous process plates are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 with a nitinol spring conforming to ASTM F2063 and a coating of commercially pure titanium conforming to ASTM F1580. Additionally, the

plates feature a titanium coating on their medial surfaces as well as the initial portion of the barrel.

Indications for Use
Spinal Elements' Spinous Process Plate System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1) of skeletally mature patients. It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), trauma (i.e. fracture or dislocation), spondylolisthesis, and/or tumor. Spinal Elements' Spinous Process Plate System is not intended for stand-alone use.

Substantial Equivalence
The subject device is substantially equivalent to the predicate devices cleared in K151863 *Reli SP Spinous Plating System* (PRIMARY), K123246 *CD HORIZON SPIRE* and K100354 *PrimaLOK sp Interspinous Fusion System*.

Technological Characteristics
The subject device has equivalent technological characteristics to its predicates presented below through comparison in areas including labeling/indications for use, general design features, dimensions, function, materials and instrumentation to the following predicate devices:

- Reli SP Spinous Plating System (K151863) - PRIMARY
- CD HORIZON SPIRE (K123246)
- PrimaLOK sp Interspinous Fusion System (K100354)

Performance Data
No clinical testing was found to be necessary. Non-clinical performance testing included:

- Static Compression and Torsion testing per ASTM F 1717
- Dynamic Compression Testing per ASTM F 1717
- Plate Dissociation per ASTM F1798
- Pullout Testing
- Particulate Analysis per ASTM F1877
- Corrosion testing per ASTM F2129
- Austenitic finish (A_f) functional testing

All data indicates that the device will perform as intended.

Conclusion
Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject device has been shown to be substantially equivalent to the aforementioned predicate devices cleared by FDA for commercial distribution in the United States.