



September 6, 2018

Spinal Elements, Inc.  
Julie Lamothe, Ph.D., MBA  
Senior Director, Regulatory Affairs  
3115 Melrose Drive, Suite 200  
Carlsbad, California 92010

Re: K180728

Trade/Device Name: Spinal Elements Cerclage System  
Regulation Number: 21 CFR 888.3010  
Regulation Name: Bone fixation cerclage  
Regulatory Class: Class II  
Product Code: OWI, JDQ  
Dated: July 9, 2018  
Received: July 10, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

<https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Ronald P. Jean -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)

K180728

Device Name

Spinal Elements Cerclage System

Indications for Use (Describe)

The Spinal Elements Cerclage System is intended for use in cardiovascular surgery. The indications for use include cardiovascular surgery for closure of the sternum following sternotomy. The system is intended to provide temporary stabilization during the development of solid bony fusion.

The Spinal Elements Cerclage System is a temporary implant to be used in orthopedic surgery. The Spinal Elements Cerclage System is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. The Spinal Elements Cerclage System is designed for a posterior approach. The indications for use include the following applications:

1. Spinal trauma surgery: The Spinal Elements Cerclage implants can be used in sublaminar wiring techniques;
2. Spinal degenerative surgery: The Spinal Elements Cerclage implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of 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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*Spinal Elements, Inc.  
Premarket Notification – Spinal Elements Cerclage System*

## **510(k) Summary Spinal Elements Cerclage System**

**510(k) Number: K180728**

### **Manufacturer Identification**

#### **Submitted By:**

Spinal Elements, Inc.  
3115 Melrose Drive, Suite 200  
Carlsbad, CA 92010  
760-607-0121  
760-607-0125 (fax)

#### **Contact Information:**

Julie Lamothe  
Spinal Elements, Inc.  
3115 Melrose Drive, Suite 200  
Carlsbad, CA 92010  
760-607-1816  
760-607-0125 (fax)  
jlamothe@spinalelements.com

#### **Date Prepared:**

July 9<sup>th</sup>, 2018

### **Device Identification**

#### **Proprietary Name**

Spinal Elements Cerclage System

#### **Common Name**

Cerclage

#### **Device Classification**

21 CFR 888.3010 - Bone fixation cerclage

#### **Proposed Regulatory Class**

Class II

#### **Device Product Code**

OWI, JDQ

### **Device Description**

The Spinal Elements Cerclage System consists of a strap manufactured from PEEK conforming to ASTM F2026 compounded with 7.5% barium sulphate for radiopacity. The leading tip of the device is comprised of a spherical feature followed by a tapered neck to allow for an instrument to assist in advancing the strap around the bony structures to be secured. The spherical tip contains a tantalum pin for visualization when fluoroscopic imaging is used. The device has teeth along its length that interact with a latching mechanism at the opposite end of the strap. The latch allows a loop created by feeding the strap through the latch to be made consecutively shorter or taught by continuing to pull the strap through the latch. Prior to creating the loop, the spherical tip of the device is cut off and discarded to allow for the strap to pass through the latch. The latch resists the lengthening of the loop due to forces that would pull the strap in the opposite direction, thereby securing the structures intended to be fixed.

Once the desired loop length is reached, the unneeded portion of the strap may be cut off and discarded.

**Indications for Use**

The Spinal Elements Cerclage System is intended for use in cardiovascular surgery. The indications for use include cardiovascular surgery for closure of the sternum following sternotomy. The system is intended to provide temporary stabilization during the development of solid bony fusion.

The Spinal Elements Cerclage System is a temporary implant to be used in orthopedic surgery. The Spinal Elements Cerclage System is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. The Spinal Elements Cerclage System is designed for a posterior approach. The indications for use include the following applications:

1. Spinal trauma surgery: The Spinal Elements Cerclage implants can be used in sublaminar wiring techniques;
2. Spinal degenerative surgery: The Spinal Elements Cerclage implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

**Substantial Equivalence**

The subject device is substantially equivalent to the primary predicate device *Implanet Jazz Lock* cleared in K153348.

**Technological Characteristics**

The subject device was established as substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, operating principle and function.

**Performance Data**

In support of this 510(k) Premarket Notification, Spinal Elements has conducted non-clinical testing demonstrating that the Spinal Elements Cerclage System provides adequate mechanical strength for its intended use and is substantially equivalent to its predicate device. The testing included static and dynamic testing of the Cerclage construct strength as well as relative abrasion testing to determine the propensity for the implant to cut into bone. Creep testing was also performed, and the Cerclage implant showed adequate resistance to plastic deformation.

**Conclusion**

Based on the indication for use, technological characteristics, and comparison to predicate devices, the Spinal Elements Cerclage System has been shown to be substantially equivalent to legally marketed predicate devices.