



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Spinal Elements, Incorporated  
Ms. Julie Lamothe  
Regulatory Affairs Director  
3115 Melrose Drive, Suite 200  
Carlsbad, California 92010

June 3, 2015

Re: K151215  
Trade/Device Name: MERCURY<sup>®</sup> Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNI, MNH, KWP, KWQ  
Dated: May 5, 2015  
Received: May 6, 2015

Dear Ms. 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 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,

**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)

K151215

Device Name

MERCURY® Spinal System

Indications for Use (Describe)

The Mercury® Spinal System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

This system is intended to be used with 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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*Spinal Elements, Inc.*  
*Premarket Notification – Mercury® Spinal System – Line Additions*

## **510(k) Summary** **Mercury® Spinal System**

### **Manufacturer Identification**

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

### **Contact Information:**

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Regulatory Affairs Director  
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**Date Prepared:** May 5<sup>th</sup> 2015

<b>Proprietary Name</b>	Mercury® Spinal System
<b>Common Name</b>	Pedicle Screw Spinal System
<b>Device Classification</b>	21 CFR Section 888.3070 - Pedicle Screw Spinal System
<b>Proposed Regulatory Class</b>	Class III
<b>Device Product Code</b>	NKB, MNI, MNH, KWP, KWQ

### **Purpose of this 510(k)**

This 510(k) seeks clearance for line additions to the Mercury® Spinal System previously cleared for use under K071914, K082353, K083230, K091587 and K141372.

### **Device Description**

Spinal Elements' Mercury Spinal System is comprised of a variety of screws, hooks, rods, connectors, and staples that are used for attachment to the non-cervical spine (the thoracic spine through the sacrum and in the ilium). A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient. Rods span the distance between screws and hooks and achieve fixation by the mechanical joining of the rods with the screws or hooks. Connectors are used to mechanically join one rod to another. Staples (when used) are placed under the head of the screws to help distribute loads placed against the bone.

Screws, hooks, rods, connectors, and staples are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 and ISO 5832-3 or ASTM F 1472. Additionally, some rods

*Spinal Elements, Inc.*  
*Premarket Notification – Mercury® Spinal System – Line Additions*

may be manufactured from cobalt chromium alloy (Co-Cr) conforming to ASTM F 1537 and ISO 5832-12.

**Indications for Use**

The Mercury® Spinal System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

This system is intended to be used with bone graft.

**Substantial Equivalence**

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

- Spinal Elements' Mercury Spinal System (K071914, K083230, K082353, K091587, K141372)

**Performance Data**

Performance testing included:

- Static Axial Grip and Torsional Grip Interconnection Testing per ASTM F 1798
- Static and Dynamic Flexion/Extension Testing per ASTM F 1798

All data indicates that the device will perform as intended.