September 16, 2019

Spinal Elements, Inc
Julie Lamothe, Ph.D., MBA
Vice President of Regulatory Affairs & Quality Assurance
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K191576
Trade/Device Name: Mercury® Spinal System, Overwatch® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: June 12, 2019
Received: June 14, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191576

Device Name
Mercury® Spinal System; Overwatch® Spinal System

Indications for Use *(Describe)*
The Mercury® and Overwatch® Spinal Systems are 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 (Tl -S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. These systems are 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.

These systems are intended to be used with bone graft.

The Spinal Elements Mercury Fixation System may be used in conjunction with the Spinal Elements Overwatch System. In order to achieve additional levels of fixation, the Mercury or Overwatch Fixation Systems may be connected to 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 or Overwatch Spinal Systems. Refer to the Lotus Posterior Cervical/Thoracic Spinal System package insert for a list of Lotus indications for use.

When used for posterior non-cervical pedicle screw fixation in pediatric patients the Mercury and Overwatch implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary
# Mercury® and Overwatch Spinal Systems

**510(k) Number _____**

**Manufacturer Identification**

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

**Contact Information:** Julie Lamothe
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**Date Prepared:** June 12th, 2019

**Device Identification**

| | |
|---|---|
| **Proprietary Name** | Mercury® Spinal System; Overwatch® Spinal System |
| **Common Name** | Pedicle Screw Spinal System |
| **Device Regulation Name** | Thoracolumbosacral Pedicle Screw System |
| **Device Classification** | 21 CFR Section 888.3070 |
| **Proposed Regulatory Class** | Class II |
| **Device Product Code** | NKB, KWP, KWQ |

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

The Overwatch Spine System consists of spinal implants for fixation of the thoracolumbar and/or sacral spine. The system includes rods, screws, set screws, transverse crosslinks, rod connectors, and hooks. The Overwatch screws are self-tapping and are available with either a cancellous or a dualfix thread design. They are available in cannulated and noncannulated configurations, in a variety of diameters and lengths. The system implants are manufactured from Ti-6Al-4V (ASTM F136).

The Overwatch Spine System is a multiple component system comprised of spinal implants for fixation of the thoracolumbar and/or sacral spine. The system includes rods, pedicle screws, set screws, transverse crosslinks, rod connectors, and hooks. When assembled, the components create a rigid structure to provide stabilization and promote spinal fusion. The systems screws are self-tapping and are available with either a cancellous or cortical cancellous dualfix thread design. The tulips are offered in low top, extended tab and tower configurations. All implant components of the Overwatch Spine System are manufactured from Ti-6Al-4V (ASTM F136) and are provided non-sterile for single-use. The system is to be used with bone graft material to facilitate spinal fusion.

**Indications for Use**

The Mercury® and Overwatch® Spinal Systems are 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 (Tl -S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. These systems are 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.

These systems are intended to be used with bone graft.

The Spinal Elements Mercury Fixation System may be used in conjunction with the Spinal Elements Overwatch System. In order to achieve additional levels of fixation, the Mercury or Overwatch Fixation Systems may be connected to 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 or Overwatch Spinal Systems. Refer to the Lotus Posterior Cervical/Thoracic Spinal System package insert for a list of Lotus indications for use.

When used for posterior non-cervical pedicle screw fixation in pediatric patients the Mercury and Overwatch implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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

- Primary Predicate: Overwatch Spinal System K161842
- Additional Predicates are for Mercury Spinal System (K083230, K091587, K141372, and K151215)

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

**Performance Data**
Performance testing included:

- Static Axial Grip testing per ASTM F1798
- Static Torsional Grip testing per ASTM F1798
- Dynamic Compression Bending per ASTM F 1717
- Dynamic Flexion-Extension testing per ASTM F1798
- Interconnection Strength testing per ASTM F1798

All data indicates that the devices will perform as intended.

**Conclusions**
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.