April 10, 2018

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

Re: K172967
Trade/Device Name: Mercury® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: March 26, 2018
Received: March 28, 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. 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.

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.

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) 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

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)*
K172967

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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510(k) Summary
Mercury® Spinal System

510(k) Number K172967

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

Contact Information: Julie Lamothe
Senior Director, Regulatory Affairs/Quality Assurance
Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
760-607-1816
jlamothe@spinalelements.com

Date Prepared: September 20th 2017

Proprietary Name	Mercury® Spinal System
Device Classification	21 CFR Section 888.3070
Proposed Regulatory Class	Class II
Device Product Code	NKB, 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, K141372 and K151215.

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 into 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, ASTM F 1472 or ISO 5832-3. Additionally, some rods 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:

- The primary predicate device is Spinal Elements' Mercury Spinal System K071914
- Additional predicate devices are Spinal Elements' Mercury Spinal System (K083230, K082353, K091587, K141372, K151215)

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, function, material, manufacturing process and instrumentation:

- Spinal Elements Mercury Spinal System K071914 - Primary

Performance Data

Performance testing included:

- Static Axial Grip and Torsional Grip Interconnection Testing per ASTM F 1717 and ASTM F 1798
- Static and Dynamic Flexion/Extension Testing per ASTM F 1798

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.