December 1, 2022

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

Re: K222516
Trade/Device Name: Mercury® II Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, OLO
Dated: September 7, 2022
Received: September 8, 2022

Dear Julie 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222516

Device Name
Mercury® II Spinal System

Indications for Use *(Describe)*
The Mercury® II 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.

The Spinal Elements Mercury II Spinal System may be used in conjunction with the Spinal Elements Overwatch System. In order to achieve additional levels of fixation, the Mercury II 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 II 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 II and Overwatch implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

Spinal Elements' fenestrated screws are intended to be used with saline or radiopaque dye.

These devices are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Spinal Elements' Navigated Instruments are intended to be used during the preparation and placement of Spinal Elements' Mercury® II screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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® II Spinal System

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
Vice President, Regulatory Affairs & Quality Assurance
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Date Prepared: August 17th, 2022

Device Identification

Proprietary Name	Mercury® II Spinal System
Common Name	Pedicle Screw Spinal System
Device Regulation Name	Thoracolumbosacral Pedicle Screw System, Appliance, Fixation, Spinal Interlaminal, Appliance, Fixation Spinal Intervertebral Body, Orthopedic Stereotaxic Instrument,
Device Classification	21 CFR Section 888.3050, 888.3060, 888.3070, 882.4560
Proposed Regulatory Class	Class II
Device Product Code	NKB, KWP, KWQ, OLO

Device Description

Spinal Elements' Mercury II Spinal System is comprised of a variety of screws and rods 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 achieve fixation by the mechanical joining of the rods with screws.

Screws and rods are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3. Additionally, some rods may be manufactured from cobalt-chrome alloy (Co-Cr) conforming to ASTM F1537 or ISO 5832-12.

Navigated instruments are surgical instruments manufactured from stainless steel, as specified in ASTM F899 or ASTM A564. Navigated instruments are non-sterile and are intended to be used with the Medtronic StealthStation® S7 and S8 System.

Indications for Use

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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: Mercury® and Overwatch® Spinal Systems (K191576)
- Additional Predicate: Mercury® Spinal System (K083230, K091587, K141372, K151215, and K172967)
- Additional Predicate: Mercury Navigated Instruments (K190881)
- Additional Predicate: Janus Fenestrated Screws (K180179)

Technological Characteristics
The subject device was established as substantially equivalent to another predicate device 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 device through comparison in areas including design, intended use, and function.

Performance Data
Performance testing included:

- Static Testing per ASTM F1798 and ASTM F543
- Dynamic Testing per ASTM F 1717 and 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.