February 21, 2025

Spinal Elements Inc.
Cheryl Allen
Associate Director, Regulatory Affars
3115 Melrose Drive
Suite 200
Carlsbad, California 92010

Re: K243916
Trade/Device Name: Primus Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ, OLO
Dated: December 20, 2024
Received: December 20, 2024

Dear Cheryl Allen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K243916

Device Name
Primus Spinal Fixation System

Indications for Use *(Describe)*
The Primus Spinal Fixation 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 Primus Spinal Fixation System may be used in conjunction with the Spinal Elements Overwatch System. In order to achieve additional levels of fixation, the Primus 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 Primus 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 Primus 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' Primus 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.

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

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510(k) Summary
Primus Spinal Fixation System

Date: December 19, 2024

I. SUBMITTER

Company Information: Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010

Contact Information: Cheryl Allen
Associate Director, Regulatory Affairs
760-607-1840
callen@spinalelements.com

II. DEVICE

Proprietary Name	**Primus Spinal Fixation System**
Common Name	Pedicle Screw Spinal System
Regulation Name	Thoracolumbosacral pedicle screw system
Device Classification	888.3070, 888.3050, 888.3060, 882.4560
Proposed Regulatory Class	Class II
Device Product Code	NKB, KWP, KWQ, OLO

III. DEVICE DESCRIPTION

Spinal Elements' Primus Spinal Fixation System is comprised of a variety of screws, hooks, rods, and connectors 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.

Navigation instruments are non-sterile and are intended to be used with the Medtronic StealthStation® S7 and S8 System.

IV. INDICATIONS FOR USE

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V. TECHNOLOGICAL CHARACTERISTICS OF DEVICE

Primus Spinal Fixation System is identical or similar to the predicate system with regard to intended use/indications for use, device description, technological characteristics (design, components, material, and principle of operation, manufacturing, labeling, sterility and packaging) and non-clinical performance (i.e. mechanical testing). This Traditional 510(k) seeks clearance for minor modifications to the locking mechanism, component dimensions, and instrumentation of the system previously cleared under 510(k) K222516. The intended use, indication for use, technological characteristics, performance characteristics, packaging and labeling, and sterilization and the fundamental scientific technology remain the same.

VI. PERFORMANCE DATA

Mechanical testing

The subject device has the same performance characteristics as the previously cleared predicate device and devices detailed in a representative data summary published by Jonathon Peck et. al. Non-clinical testing consisted of the following testing performed in accordance with the FDA Guidance for Industry and FDA Staff: Spinal System 510(k)s MAY 2004.

- Static and Dynamic Compression Bending Testing per ASTM F1717-21
- Static Torsion Testing per ASTM F1717-21
- Tensile Dissociation, Neutral and Max Angle Testing per ASTM F1798-21

Testing conducted demonstrates substantial equivalence to the predicate device.

VII. SUBSTANTIAL EQUIVALENCE

Primus Spinal Fixation System has been found to be substantially equivalent to the primary predicate with respect to intended use/indications for use, device description, technological characteristics and performance. The information provided in this premarket submission supports substantial equivalence to the predicate device.

- Primary Predicate: Mercury® II Spinal System (K222516)