June 17, 2020

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

Re: K201029
Trade/Device Name: Sapphire® Spinal System, Sapphire X Anterior Cervical Plate Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 20, 2020
Received: April 20, 2020

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, M.B.E.
Acting 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)*
K201029

Device Name
Sapphire® Spinal System

Indications for Use *(Describe)*
The Sapphire® Spinal System is intended for anterior cervical fixation (C2-T1) in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal stenosis
- Deformities or Curvatures (kyphosis, lordosis or scoliosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K201029

Device Name
Sapphire X Anterior Cervical Plate Spinal System

Indications for Use *(Describe)*
The Sapphire X Anterior Cervical Plate Spinal System is intended for anterior cervical fixation (C2-T1) in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal stenosis
- Deformities or Curvatures (kyphosis, lordosis or scoliosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

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)

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510(k) Summary
Sapphire® Spinal System and Sapphire X Anterior Cervical Plate 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
Spinal Elements, Inc.
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jlamothe@spinalelements.com

Date Prepared: June 15th, 2020

Device Identification

Proprietary Name	Sapphire® Spinal System; Sapphire X Anterior Cervical Plate Spinal System
Common Name	Anterior fixation
Device Regulation Name	Spinal intervertebral body fixation orthosis
Device Classification	21 CFR Section 888.3060
Proposed Regulatory Class	Class II
Device Product Code	KWQ

Purpose of this 510(k)

This Traditional 510(k) seeks clearance for a new anterior cervical plate system (Sapphire X), a modification (line addition) and a screw design modification to Spinal Elements' Sapphire Spinal System previously cleared under K101848. The new devices have an identical intended use and fundamental scientific technology as the predicate.

Device Description

Spinal Elements' Sapphire® Spinal System and Sapphire X Anterior Cervical Plate Spinal System are comprised of plates and screws that are used for attachment to the anterior cervical spine. Both plates and screws are available in a variety of sizes to suit the individual pathology and anatomic conditions of the patient. Plates are pre-shaped with radial and lordotic curvature and have large windows for graft and end plate visualization. Plates range in length to accommodate one to five levels of fusion. Sapphire X Anterior Cervical Plates

accommodate larger angles for the distal screws in order to minimize plate overhang on the vertebral bodies.

All screws are equipped with an internal locking mechanism that is actuated by rotating a preassembled inset screw. Upon rotation, the insert screw interfaces with a clip in the head of the screw causing the clip to expand. The expansion of the clip prevents the screw from disassociating from the plate. The same screws will be used for both the Sapphire® and Sapphire X Anterior Cervical Plate Systems.

Screws are available in both fixed and variable angle designs. Fixed angle screws have a predetermined trajectory relative to the plate. The fixed angle screws have a neck diameter similar in size to the screw hole diameter of the plate.

Variable angle screws provide freedom in trajectory of the screws into the vertebral body. They allow 8° of angulation in any direction relative to the plate. The variable angle screws have a neck diameter that is smaller than the screw hole diameter of the plate. This difference in diameters allows the variable angle screws to be inserted at various angles relative to the plate.

The materials used for the system remain unchanged. The plates and screws are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ISO 5832-3. The locking clips on the screws are manufactured from Nitinol conforming to ASTM F2063.

Indications for Use

The Sapphire® Spinal is intended for anterior cervical fixation (C2-T1) in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal stenosis
- Deformities or Curvatures (kyphosis, lordosis or scoliosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

The Sapphire X Anterior Cervical Plate Spinal System is intended for anterior cervical fixation (C2-T1) in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal stenosis
- Deformities or Curvatures (kyphosis, lordosis or scoliosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

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

- Primary Predicate: Sapphire Spinal System K101848
- Additional Predicate: MaxAn Spinal System K133518

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 compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Dynamic compression bending per ASTM F1717 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.