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

August 2, 2023

Re: K231593
Trade/Device Name: Sapphire X3 Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 31, 2023
Received: June 1, 2023

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2023.08.02 12:14:34 -04'00'

for

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)*
K231593

Device Name
Sapphire X3 Anterior Cervical Plate System

Indications for Use *(Describe)*
The Sapphire X3 Anterior Cervical Plate 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.

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510(k) Summary
Sapphire X3 Anterior Cervical Plate System

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
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Carlsbad, CA 92010
760-607-0121

Contact Information: Julie Lamothe
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Date Prepared: May 31, 2023

Device Identification

Proprietary Name	Sapphire X3 Anterior Cervical Plate 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

Device Description

The purpose of this submission is to seek clearance for additional implant sizes in the Sapphire X3 Anterior Cervical Plate System. The Spinal Elements' Sapphire X3 Anterior Cervical Plate System is 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 X3 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.

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 diameter 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 X3 Anterior Cervical Plate 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)
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- Spinal stenosis
- Deformities or Curvatures (kyphosis, lordosis or scoliosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Predicate Devices
Primary Predicate: Ceres Midline Spinal System (previously the Amendia Cervical Plate System) - K152455
Additional Predicate: Sapphire X Anterior Cervical Plate System - K201029

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

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

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.