August 19, 2022

Surgalign Spine Technologies
Jessica Jho
Director, Regulatory Affairs
520 Lake Cook Road Suite 315
Deerfield, Illinois 60015

Re: K221403
Trade/Device Name: Cortera Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 12, 2022
Received: August 15, 2022

Dear Jessica Jho:

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,

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)*
K221403

Device Name
Cortera™ Spinal Fixation System

Indications for Use *(Describe)*

The Cortera™ Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (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; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Cortera™ Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Cortera™ Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The Cortera™ Spinal Fixation System is intended to be used with an autograft and/or allograft.

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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This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER:

Surgalign Spine Technologies
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Deerfield, IL 60015 USA

Contact Person: Jessica Jho
Director of Regulatory Affairs
Surgalign Spine Technologies
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(801) 455-9267

Date Summary Prepared: August 19, 2022

II. DEVICE

Trade or Proprietary Name: Cortera™ Spinal Fixation System
Common Name: Thoracolumbosacral pedicle screw system

Regulation Number: 21 CFR §888.3070
Classification: Class II
Product Code: NKB, Thoracolumbosacral pedicle screw system

III. LEGALLY MARKETED PREDICATE DEVICES

Predicate Device		
510(k)	**Product Name**	**Clearance Date**
K192938	Invictus Spinal Fixation System	December 12, 2019
Reference Device		
510(k)	**Product Name**	**Clearance Date**
K192800	Streamline TL Spinal Fixation System	January 14, 2020

IV. DEVICE DESCRIPTION

The Cortera™ Spinal Fixation System is a Thoracolumbosacral pedicle screw system intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or the sacral spine. The System consists of screws, rods, locking set screws and associated manual surgical instruments for an open or minimally invasive surgical approach. The screws and set screws are manufacturered from titanium alloy (Ti6Al4V per ASTM F136). The rods are available in titanium alloy or cobalt chromium alloy (Co-28Cr-6Mo per ASTM F1537). The implants are available in a variety of sizes to accommodate individual patient anatomy and are provided non-sterile.

The Cortera™ Spinal Fixation System rods may be used in connection with Streamline Cross Connectors, covered in K192800. The Streamline Cross Connectors accept various rod diameters and are appropriate for use with Cortera™ Spinal Fixation System 5.5 mm diameter rod-based systems. These cross connectors will keep their original cleared trade name.

V. INDICATIONS FOR USE

The Cortera™ Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (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; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Cortera™ Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Cortera™ Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The Cortera™ Spinal Fixation System is intended to be used with an autograft and/or allograft.

VI. TECHNICAL COMPARISON TO PREDICATE

The technological design features of the subject devices, such as intended use, indications for use, design, function and technology, were compared to the predicates and it was demonstrated that they are substantially equivalent.

VII. PERFORMANCE DATA

Nonclinical testing performed on the Cortera™ Spinal Fixation System supports substantial equivalence to other predicate devices. The following testing was performed:

- Static and dynamic compression testing per ASTM F1717
- Static torsion testing per ASTM F1717
- Axial Pulloff (F_x) testing per ASTM F1798

The results demonstrate that the subject Cortera™ Spinal Fixation System is substantially equivalent to other predicate devices.

VIII. CONCLUSION

Based on the information provided in this 510(k) submission, it has been determined that the subject devices are substantially equivalent to the legally marketed devices in regards to indication for use, intended use, design, technology, and performance.