Xtant Medical Holdings, Inc.
Rebecca Lennemann
VP, Quality and Regulatory Affairs
664 Cruiser Lane
Belgrade, Montana 59714

August 2, 2024

Re: K241892
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: June 28, 2024
Received: June 28, 2024

Dear Rebecca Lennemann:

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.

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.08.02 11:48:29 -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241892

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.

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510(k) Summary
(in accordance with 21 CFR 807.92)

Submission Date:	28 June 2024
Submitter:	Xtant Medical Holdings, Inc. 664 Cruiser Lane Belgrade, MT 59714
Submitter and Official Contact:	Ms. Rebecca Lennemann Director, RA/QA Xtant Medical Holdings, Inc. 664 Cruiser Lane Belgrade, MT 59714 +1 (406) 924-5878 rlennemann@xtantmedical.com
Manufacturing Site:	Xtant Medical Holdings, Inc. 664 Cruiser Lane Belgrade, MT 59714
Trade Name:	Cortera™ Spinal Fixation System
Classification Name:	Thoracolumbosacral pedicle screw system
Classification Regulation / Product Code	21 CFR §888.3070 / NKB

Substantially Equivalent Devices:

Proposed Xtant Medical Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Cortera™ Spinal Fixation System	K221403	Surgalign Spine Technologies / Cortera Spinal Fixation System (Primary Predicate)
	K192800	Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.) / Streamline TL Spinal Fixation System (Additional Predicate)

510(k) Summary
(in accordance with 21 CFR 807.92)

Device Description:

The Cortera Spinal Fixation System (Cortera 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 Cortera System consists of screws, rod-to-rod connectors, lateral offset connectors, rods, locking set screws and associated reusable manual surgical instruments for an open or minimally invasive surgical approach. The screws, rod-to-rod connectors, lateral offset connectors, and set screws are manufactured 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. A variety of these implant configurations were previously covered in K221403.

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

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.

510(k) Summary
(in accordance with 21 CFR 807.92)

Technology Comparison: The Cortera™ Spinal Fixation System (Cortera System) employs the same technological characteristics as the predicate device.

Characteristic	***Surgalign Spine Technologies Cortera Spinal Fixation System (K221403)***	***Xtant Medical Holdings, Inc. Cortera™ Spinal Fixation System (Proposed Device)***	***Discussion of Differences***
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.	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.	Same.
Regulation / Product Code	21 CFR §888.3070 / NKB	21 CFR §888.3070 / NKB	Same.

510(k) Summary
(in accordance with 21 CFR 807.92)

Technology Comparison (continued):

Characteristic	***Surgalign Spine Technologies Cortera Spinal Fixation System (K221403)***	***Xtant Medical Holdings, Inc. Cortera™ Spinal Fixation System (Proposed Device)***	***Discussion of Differences***
Screws	• Solid Polyaxial Pedicle Screws • Cannulated Polyaxial Pedicle Screws • Cannulated Polyaxial MIS Screws • Solid Polyaxial Cortical Cancellous Screws • Cannulated Polyaxial Cortical Cancellous Screws • Cannulated Polyaxial Cortical Cancellous MIS Screws	• Solid Polyaxial Pedicle Screws • Cannulated Polyaxial Pedicle Screws • Cannulated Polyaxial MIS Screws • Solid Polyaxial Cortical Cancellous Screws • Cannulated Polyaxial Cortical Cancellous Screws • Cannulated Polyaxial Cortical Cancellous MIS Screws • Solid Polyaxial Reduction Pedicle Screws • Cannulated Polyaxial Reduction Pedicle Screws • Solid Polyaxial Cortical-Cancellous Reduction Screws • Cannulated Polyaxial Cortical-Cancellous Reduction Screws	This 510(k) includes the addition of reduction screws, rod-to-rod connectors and lateral offset connectors to the predicate device Cortera Spinal Fixation System cleared by FDA in K221403.
Cross Connectors	• Variable Length Cross Connector • Fixed Length Cross connector	• Variable Length Cross Connector • Fixed Length Cross connector	
Rod-to-Rod Connectors:	NA	• Open-Open, Open-Side, Closed 4 Hole, and Open-Closed, • Titanium Alloy	
Lateral Offset Connectors	NA	• Lateral Offset and Closed Lateral Offset • Titanium Alloy	
Rods	*Rods:* • CoCr Straight • CoCr Pre-Bent • Titanium Alloy, Straight • Titanium Alloy, Pre-Bent	*Rods:* • CoCr Straight • CoCr Pre-Bent • Titanium Alloy, Straight • Titanium Alloy, Pre-Bent	
Cleaning	• Manual, OR • Pre-cleaning, and • Automated washer.	• Manual, OR • Pre-cleaning, and • Automated washer.	Same
Sterilization	Non-sterile devices provided with validated steam sterilization parameters to ensure a sterility assurance level (SAL) of 10^{-6}. Parameters: • Cycle: Pre-vacuum (wrapped • Temperature: 132°C (270°F) • Recommended exposure time: 4 minutes • Recommended dry time: 40 minutes	Non-sterile devices provided with validated steam sterilization parameters to ensure a sterility assurance level (SAL) of 10^{-6}. Parameters: • Cycle: Pre-vacuum (wrapped • Temperature: 132°C (270°F) • Recommended exposure time: 4 minutes • Recommended dry time: 30 minutes	The sterilization recommended dry time was changed from 40 minutes (predicate device) to 30 minutes (subject device).

510(k) Summary
(in accordance with 21 CFR 807.92)

Performance Testing:

Reprocessing The Cortera System was verified and validated for performance in accordance with internal requirements and the following guidance document:

- *FDA Guidance Document: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, dated 17 March 2024.*
- *AAMI/ANSI ST79: 2017, Am1: 2020, Am2: 2020, Am3: 2020, Am4: 2020, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
- *ISO 17665-1: 2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.*

Verification and validation results indicate that the Cortera System complies with its predetermined specifications and the applicable guidance document.

Biocompatibility The Cortera System was verified and validated for performance in accordance with internal requirements and the following guidance document:

- *FDA Guidance Document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", dated 08 September 2023.*
- *ISO 10993-1: 2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing with a risk management process.*

Verification and validation results indicate that the Cortera System complies with its predetermined specifications and the applicable guidance document.

510(k) Summary
(in accordance with 21 CFR 807.92)

Performance Testing (continued):

Performance Testing – Bench

The Cortera System was verified and validated for performance in accordance with internal requirements and the following guidance document:

- *FDA Guidance Document: Spinal System 510(k)s, dated 03 May 2004.*
- *ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*
- *ASTM F899-20, Standard Specification for Wrought Stainless Steels for Surgical Instruments.*
- *ASTM F1537-20, Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).*
- *ASTM F2063-18, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.*
- *ASTM F1717-21, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.*
- *ASTM F1798-21, Standard Test Methods for Evaluating Statis and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.*

Verification and validation results indicate that the Cortera System complies with its predetermined specifications and the applicable guidance document.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Cortera System. The results of these activities demonstrate that the Cortera System is substantially equivalent to the predicate device when used in accordance with its intended use and labeling.

Therefore, the Cortera System is considered substantially equivalent to the predicate device.