March 4, 2026

SpineCraft, LLC
Ami Akallal-Asaad
Vice President, Regulatory Affairs & QA
777 Oakmont Lane
Westmont, Illinois 60559

Re: K260015
Trade/Device Name: ANTERIS Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 30, 2025
Received: January 5, 2026

Dear Ami Akallal-Asaad:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

MAZIAR SHAH-MOHAMMADI
-S

[For] 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260015

Please provide the device trade name(s).

ANTERIS Thoracolumbar Plate System

Please provide your Indications for Use below.

The ANTERIS Thoracolumbar Plate System Plates are intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability, or via the anterior surgical approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Trauma (i.e. fractures, including dislocation and subluxation), tumors, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, deformities (i.e. scoliosis, kyphosis, or lordosis), spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary: ANTERIS Thoracolumbar Plate System

Submitter	SpineCraft, LLC 777 Oakmont Lane Westmont, IL 60559 USA Tel: 1 630-920-7300. Fax: 1 630-920-7310
Contact Person:	Ami Akallal-Asaad VP, Regulatory Affairs & QA SpineCraft, LLC
Date Prepared:	February 27, 2026
Trade Names:	ANTERIS Thoracolumbar Plate System
Common Name:	Spinal intervertebral body fixation orthosis
Classification:	Class II
Product Code and Classification Name:	KWQ Appliance, Fixation, Spinal Intervertebral Body (21 CFR 888.3060)
Predicate Devices:	**Primary Predicates:**
	Product Code: KWQ — Product Name / 510 (k): Raven Anterior Lumbar Plate (K183214)
	Additional Predicates:
	KWQ — Presidio Anterior Lumbar Plate System (K132589)
Device Description:	The ANTERIS Thoracolumbar Plate System is an anterior, anterolateral, or lateral plate fixation system intended for use in the thoracic, lumbar, and sacral spine (T1-S1). The plates are pre-contoured to accommodate anatomical alignment and incorporate a central vertical slot to facilitate visualization and graft placement. The ANTERIS plates are offered in standard and optional large versions. Screw back-out is prevented through the use of anti-backout caps. The system is intended to provide temporary stabilization and support to promote the development of a solid spinal fusion. The ANTERIS Thoracolumbar Plate System consists of plates and bone screws made from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.
Intended Use/Indication for Use:	The ANTERIS Thoracolumbar Plate System Plates are intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability, or via the anterior surgical approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: Trauma (i.e. fractures, including dislocation and subluxation), tumors, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, spondylolisthesis, deformities (i.e. scoliosis, kyphosis, or lordosis), spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

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Technological Characteristics:	As established in this submission, the subject ANTERIS Thoracolumbar Plate System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and to have similar technological characteristics to its predicate devices through design, intended use, material composition, function, and range of sizes.
Performance Data:	The purpose of this submission is to introduce the ANTERIS Thoracolumbar Plate System Non-clinical testing performed on the ANTERIS Thoracolumbar Plate System supports substantial equivalence to predicate devices. The following testing was performed: • Static Compression Bending (ASTM F1717-18) • Dynamic compression Bending (ASTM F1717-18) • Static Torsion (ASTM F1717-18) The results of non-clinical testing demonstrate that the strength and performance of the ANTERIS Thoracolumbar Plate System is substantially equivalent to legally marketed predicate devices.
Conclusion:	Based on the indications for use, technological characteristics, non-clinical performance testing, and comparison to predicate devices, the subject d ANTERIS Thoracolumbar Plate System has been shown to be substantially equivalent to legally marketed predicate devices.