February 4, 2026

Spinal Elements Inc
Cheryl Allen
Associate Director, Regulatory Affairs
3115 S. Melrose Suite 200
Carlsbad, California 92010

Re: K250773
Trade/Device Name: Luna® Ti Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 8, 2026
Received: January 9, 2026

Dear Cheryl Allen:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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.	K250773
Please provide the device trade name(s).	Page 1 of 1

Luna® Ti Interbody Fusion System

Please provide your Indications for Use below.

The Luna® Ti Interbody Fusion System consists of a Luna Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna Ti Interbody Fusion System is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients receiving the device should have had at least six months of non-operative treatment prior to receiving the Luna Ti Implant. The Luna Ti Interbody Fusion System is to be used with supplemental fixation.

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

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

510(k) Summary
Luna® Ti Interbody Fusion System

Date: September 18, 2025

I. SUBMITTER

Company Information:
Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010

Contact Information:
Cheryl Allen
Associate Director, Regulatory Affairs
760-607-1840
callen@spinalelements.com

II. DEVICE

Proprietary Name	Luna® Ti Interbody Fusion System
Regulation Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Appliance, Fixation Spinal Intervertebral Body)
Proposed Regulatory Class	Class II
Device Product Code	MAX

III. DEVICE DESCRIPTION

The Luna® Ti Interbody Fusion System devices are for use in lumbar spinal surgery. The implants have a slightly teardrop circular shape which are made of PEEK material conforming to ASTM F2026, nitinol conforming with ASTM F2063, tantalum conforming with ASTM F560, and a titanium coating conforming with ASTM F67.

The Luna® Ti Interbody Fusion System consists of a titanium coated implant and associated accessories set of disposable and re-usable accessories for use in lumbar fusion procedures to treat degenerative disc disease. The Luna® Ti Interbody Fusion System implant is provided pre-loaded and sterile within a single-use Insertion Tool. A series of vertically oriented slots allows the device to flex and enables it to be inserted from a straight cannula and then attain a closed, fixed, and circular shape upon being placed into the disc space. Once the implant is in the desired position, the device is expanded into its ultimate height and forming a bone graft pocket. Teeth on the outer surfaces of the top and bottom components engage the implant into the adjacent endplates. The devices are presented with a large opening throughout the design to allow for the placement of autograft or allogenic bone graft. These devices are intended to be placed through a posterior approach.

IV. INDICATION FOR USE

The Luna® Ti Interbody Fusion System consists of a Luna Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna Ti Interbody Fusion System is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients receiving the device should have had at least six months of non-operative treatment prior to receiving the Luna Ti Implant. The Luna Ti Interbody Fusion System is to be used with supplemental fixation.

V. TECHNOLOGICAL CHARACTERISTICS OF DEVICE

The Luna® Ti Interbody Fusion System is equivalent to the predicate devices with regard to intended use/indications for use, device description, technological characteristics (design, components, material, and principle of operation, manufacturing, labeling, sterility and packaging) and non-clinical performance (i.e. mechanical testing). This Traditional 510(k) seeks clearance for a modification of the device for the addition of a CP titanium coating (IntimateBond™ Osseoblast). No other performance specifications or manufacturing processes have been changed.

VI. PERFORMANCE DATA

Mechanical testing

The subject device has equivalent performance characteristics as the previously cleared predicate devices.

- Static and Dynamic Compression Shear Testing per ASTM F2077
- Dynamic Torsion Testing per ASTM F2077
- Dynamic Axial Compression Testing per ASTM F2077

VII. SUBSTANTIAL EQUIVALENCE

Luna® Ti Interbody Fusion System is substantially equivalent to the primary predicate device the Luna® XD (K183560), and additional predicates Luna® XD (K193172), VySpine LumiVy™ Lumbar IBF System (K223412) and Seaspine Spacer System-NanoMetalene surface technology (K201193). Luna® Ti Interbody Fusion System is equivalent to these commercially available devices with respect to intended use/indications for use, materials, device description, technological characteristics and performance. The information provided in this premarket submission supports substantial equivalence to the predicate devices. IntimateBond™ Osseoblast (with nanoscale surface features) coating is substantially equivalent to the cited legally marketed predicate devices.