U.S. FOOD & DRUG ADMINISTRATION

May 15, 2026

Spinal Elements, Inc.
Sartaj Kaur-Hurrle
Senior Regulatory Affairs Specialist
3115 Melrose Dr., Suite 200
Carlsbad, California 92010

Re: K260506
Trade/Device Name: Ventana® P/T Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 13, 2026
Received: February 17, 2026

Dear Sartaj Kaur-Hurrle:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.	K260506

Please provide the device trade name(s).

Ventana® P/T Lumbar Interbody System

Please provide your Indications for Use below.

Ventana devices are intervertebral body fusion devices intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

These devices are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

These devices are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) months' non-operative treatment prior to being treated with these devices.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

SPINAL elements

510(k) Summary

Date : 10APR2026

I. SUBMITTER

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

Contact Information: Sartaj Kaur-Hurrle
Senior Regulatory Affairs Specialist
310-980-1426
skaur-hurrle@spinalelements.com

II. DEVICE

Proprietary Name	Ventana® P/T Lumbar Interbody System
Regulation Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Appliance, Fixation Spinal Intervertebral Body)
Device Product Code	MAX
Proposed Regulatory Class	Class II
Primary Predicate Devices	K203254 Lucent 3D

III. DEVICE DESCRIPTION

The Ventana® P/T Lumbar Interbody devices are intervertebral body fusion device for use in lumbar spinal surgery and have been cleared since 2021. They may also be referred to as interbody fusion devices or interbody cages. The devices are generally box-shaped with various holes throughout their design to allow for the placement of autograft or allogenic bone graft. They include a lid which further facilitates installation of bone graft and that is closed prior to implantation. The exterior surface of the devices has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the devices from migrating once they are implanted. The Ventana® P/T device feature lattice structures on the superior, inferior, and lateral sides to help prevent subsidence and allow bony in-growth and through-growth. The Ventana® P/T and the predicate device utilize the same instrument interface feature for device insertion and positioning.

The devices submitted herein are additively manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F3001.

IV. INDICATIONS FOR USE

Ventana devices are intervertebral body fusion devices intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

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V. TECHNOLOGICAL CHARACTERISTICS OF DEVICE

The Ventana® P/T is substantially equivalent to the predicate system with regard to intended use/indications for use, device description, technological characteristics (design, components, material, and principle of operation, labeling, sterility and packaging) and non-clinical performance (i.e. mechanical testing). This submission seeks clearance for the use of a new manufacturing facility for the 3D-printing process of the devices previously cleared under K203254 (Lucent 3D), as well as adding additional lordotic implant sizes.
The intended use, indication for use, technological characteristics, performance characteristics, packaging and labeling, and sterilization and the fundamental scientific technology remain the same.

VI. PERFORMANCE DATA

Mechanical testing
The subject devices have the same performance characteristics as the previously cleared predicate devices. Non-clinical testing and/or justification in lieu of testing were provided in accordance with the FDA Guidance for Industry and FDA Staff: *Spinal System 510(k)s*

(May 2004), as applicable:

- Dynamic Compression Testing per ASTM F 2077
- Dynamic Compression Shear Testing per ASTM F 2077

Testing conducted demonstrates substantial equivalence to the predicate device.

VII. SUBSTANTIAL EQUIVALENCE

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 predicate devices cleared by FDA for commercial distribution in the United States.