



February 25, 2026

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

Re: K253559

Trade/Device Name: Ventana® A Anterior Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: January 29, 2026
Received: January 30, 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,

KATHERINE D. KAVLOCK -S

for

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

510(k) Number (if known)
K253559

Device Name
Ventana® A Anterior Lumbar Interbody System

Indications for Use (Describe)

The Ventana® A Anterior Lumbar Interbody System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The Ventana® A Anterior Lumbar System is intended for patients who have had at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

The Ventana® A Anterior Lumbar Interbody System may be used as a standalone device when used with three integrated fixation screws and has a lordotic angle of 20° or less. When an interbody device with fewer than three screws is used, supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine in addition to the integrated fixation must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine in addition to the integrated fixation.

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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510(k) Summary
Ventana® A Anterior Lumbar Interbody System

Date: February 19, 2026

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 Ventana® A Anterior Lumbar Interbody System
Common Name Intervertebral Body Fusion Device
Device Classification 21 CFR 888.3080
Proposed Regulatory Class Class II
Device Product Code OVD
Primary Predicate Device Optimus ALIF System (K132596)
Additional Devices Ventana® L (K231252)
 Lucent® L System (K170235)
 Lucent® Magnum+ (K083475)
 BEE Cage (K200429)

III. DEVICE DESCRIPTION

The Ventana® A Anterior Lumbar Interbody System is an integrated intervertebral body fusion device for use in lumbar spinal surgery. Ventana® A Anterior Lumbar Interbody System devices are provided in multiple footprints with varying lengths, widths, heights, and angles of lordosis to accommodate individual patient anatomy. All interbody spacers feature an internal graft aperture for placement of graft material to promote fusion through the cage. The devices include a lid which further facilitates the installation of bone graft.

The interbody devices are additively manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F3001 and machined titanium alloy (Ti-6Al-4V ELI) components conforming to ASTM F136. The interbody device includes three screw holes to accept bone screws that are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 in varying lengths and diameters.

All implants are intended for single patient use only and should not be reused (used in additional patients) under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems.

IV. INDICATION FOR USE

The Ventana[®] A Anterior Lumbar Interbody System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The Ventana[®] A Anterior Lumbar System is intended for patients who have had at least six (6) months of non-operative treatment prior to being treated with the device. The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

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V. TECHNOLOGICAL CHARACTERISTICS OF DEVICE

Ventana[®] A Anterior Lumbar Interbody System devices are identical or similar to cited predicate systems in regard to intended use/indications for use, device description, technological characteristics (design, components, material, chemical composition, and principle of operation, manufacturing, labeling, sterility, etc.) and non-clinical performance (i.e. mechanical testing).

VI. PERFORMANCE DATA

Mechanical testing

The subject device has the same performance characteristics as the previously cleared predicate devices. Non-clinical testing consisted of the following testing performed in accordance with the FDA guidance Class II Special Controls Guidance Document:

Intervertebral Body Fusion Device:

- Static Axial Compression and Compression Shear Testing per ASTM F2077
- Dynamic Axial Compression and Compression Shear Testing per ASTM F2077
- Subsidence Testing per ASTM F2267
- Expulsion
- Characterization of Wear Particles per ASTM F1877
- Screw Pushout Testing

Testing demonstrates substantial equivalence to the predicate devices.

VII. SUBSTANTIAL EQUIVALENCE

Ventana[®] A Anterior Lumbar Interbody System devices have been found to be substantially equivalent to the predicate devices with respect to intended use/indications for use, device description, technological characteristics and performance. The information provided in this premarket submission supports substantial equivalence to the predicate devices.