



August 3, 2026

Elevation Spine
% Jen McBride
Regulatory Consultant
MRC Global, LLC
9160 Hwy. 64 Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

Re: K261408
Trade/Device Name: SABER-XA System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, KWQ, MAX
Dated: July 6, 2026
Received: July 7, 2026

Dear Ms. McBride:

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.

K261408

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Please provide the device trade name(s).

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SABER-XA System

Please provide your Indications for Use below.

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The Elevation Spine SABER-XA System is indicated for intervertebral fusion in patients with DDD at one or two contiguous levels from L1 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The SABER-XA Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The Elevation Spine SABER-XA Anterior Lumbar Plate, when used with screws and without the SABER-XA spacer component, is intended for anterior screw fixation to the lumbosacral spine (L1-S1) to treat instability resulting from: fracture (including dislocation and subluxation), tumor, degenerative disc disease (as defined above), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery. The Anterior Lumbar Plate is not to be used alone with Spikes, but may be used in construct with the spacer and spikes.

All interbody fusion constructs of SABER-XA System are intended to be used with FDA cleared supplemental fixation.

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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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)

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510(k) Summary

SABER-XA System

July 15, 2026

Company: Elevation Spine, Inc.
2511 Garden Rd, Suite B125
Monterey, CA 93940

Primary Contact: Jen McBride – Regulatory Consultant
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9160 Hwy 64, Ste 12
PO Box 330
Phone: (901) 481-5902
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Company/Secondary Contact: John Kirwan
VP R&D
Elevation Spine, Inc
jkirwan@elevationspine.com
413-427-6155

Trade Name: SABER-XA System

Common Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar Appliance, fixation, spinal intervertebral body

Classification: Class II

Regulation: 21 CFR 888.3080 (Intervertebral Fusion Device With Integrated Fixation, Lumbar)
21 CFR 888.3060 (appliance, fixation, spinal intervertebral body)

Panel: Orthopedic

Product Code: OVD, KWQ, MAX

Primary Predicate: Medtronic DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System – K150135

Device Description:

The SABER-XA System is an integrated fixation lumbar interbody and anterior lumbar plate system comprised of a collection of expandable lumbar interbodies, anterior plates, and fixation implants. The SABER-XA expandable interbody includes additively manufactured endplates and traditionally

manufactured internal components; the anterior plate and fixation implants are traditionally manufactured. The interbody, plate, and fixation implants are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient.

Indications for Use:

The Elevation Spine SABER-XA System is indicated for intervertebral fusion in patients with DDD at one or two contiguous levels from L1 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The SABER-XA Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The Elevation Spine SABER-XA Anterior Lumbar Plate, when used with screws and without the SABER-XA spacer component, is intended for anterior screw fixation to the lumbosacral spine (L1-S1) to treat instability resulting from: fracture (including dislocation and subluxation), tumor, degenerative disc disease (as defined above), pseudoarthrosis, spondylolysis, spondylolisthesis, scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery. The Anterior Lumbar Plate is not to be used alone with Spikes, but may be used in construct with the spacer and spikes.

All interbody fusion constructs of SABER-XA System are intended to be used with FDA cleared supplemental fixation.

Substantial Equivalence:

The subject Saber-XA components are substantially equivalent to the following predicate devices:

Primary Predicate:

- Medtronic DIVERGENCE-L™ Anterior/Oblique Lumbar Fusion System (K150135)

Additional Predicate:

- Globus Medical, Inc., MAGNIFY-S Spacer (K203278)

Reference Devices:

- Elevation Spine, SABER-C (K250240; K260660)
- Nvision Biomedical Technologies, Inc., Integral Titanium Cervical Interbody (K222015)

The subject components are similar in indications to the predicate devices. Device sizing, geometry, technological characteristics, and materials are similar to the predicate. Materials,

subtractive manufacturing, sterilization, and packaging are identical to those of the reference Elevation SABER-C (K250240) and additive manufacturing materials and processes are identical to those for SABER-C (K260660) and similar to those of the Integral Titanium Cervical Interbody (K222015).

Performance Testing:

The following bench performance testing has been conducted on the subject Saber-XA System: Static and Dynamic Axial Compression per ASTM F2077, Static and Dynamic Compression Shear per ASTM F2077, Expulsion, Subsidence per ASTM F2267, Axial screw pushout, and Plate dissociation.

Conclusion:

Based on the performance analysis and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.