April 27, 2026

Elevation Spine
% Christine Scifert
Partner
MRC Global, LLC
9160 Hwy 64, Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

Re: K260660
Trade/Device Name: SABER-C System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, KWQ, ODP
Dated: February 27, 2026
Received: March 2, 2026

Dear Christine Scifert:

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.	K260660 Page 1 of 1

Please provide the device trade name(s).

SABER-C System

Please provide your Indications for Use below.

The Elevation Spine Saber-C System is a cervical interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) and is for use in one or two adjacent spinal levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The SABER-C Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.
The SABER-C Spacer is intended to be used with supplemental fixation, such as anterior cervical plates or posterior cervical screw fixation. The SABER-C Spacer is available in a solid titanium and a porous 3D printed titanium offering. When the SABER-C Spacer is used with the SABER-C Anterior Cervical Plate and screws, the plate-spacer-screw assembly can be used as a stand-alone device with the SABER-C Anterior Cervical Plate acting as the supplemental fixation. When the SABER-C Spacer is used with the SABER-C Anterior Cervical Plate and spikes, the plate-spacer-spike assembly should be used with additional supplemental fixation such as posterior cervical screw fixation.
The SABER-C Anterior Cervical Plate, when used without the spacer component and with screws, is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis. The Anterior Cervical Plate is not to be used with spikes when used without the Spacer component.

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)

510(k) Summary

SABER-C System
February 27, 2026

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

Primary Contact: Christine Scifert – Partner
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Company/Secondary Contact: John Kirwan
VP R&D
Elevation Spine, Inc
jkirwan@elevationspine.com
413-427-6155

Trade Name: SABER-C System

Common Name: Intervertebral Fusion Device With Integrated Fixation, Cervical

Classification: Class II

Regulation: 21 CFR 888.3080 (Intervertebral Fusion Device With Integrated Fixation, Cervical)

Panel: Orthopedic

Product Code: OVE, KWQ, ODP

Primary Predicate: Elevation Spine SABER-C System – K250540

Device Description:

The SABER-C System is a cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The SABER-C System is inserted through an anterior cervical approach and is available in various geometric and material options to fit the clinical needs of the patient. The SABER-C System Anterior Cervical Plate is an anterior cervical fixation device this is available in various geometric and fixation options and can be used with various types of interbody spacers.

The previously cleared SABER-C interbody devices are offered manufactured from titanium alloy per ASTM F136 or titanium-coated radiolucent polyether ether ketone (PEEK), with titanium alloy or tantalum markers, as specified in ASTM F2026, ASTM F136, ASTM F1295, and ASTM F560. The SABER-C Anterior Cervical Plate and two fixation options, spikes or screws, are manufactured from titanium alloy, as specified in ASTM F136 and ASTM F1295. The plate is not to be used with spikes when used without the Spacer component.

The subject submission seeks to add additively manufactured components, expand size offerings, and gain clearance for minor design modifications to the previously cleared devices.

Indications for Use:

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The SABER-C Anterior Cervical Plate, when used without the spacer component and with screws, is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis. The Anterior Cervical Plate is not to be used with spikes when used without the Spacer component.

Substantial Equivalence:

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

<u>Primary Predicate:</u>

Elevation Spine SABER-C System (K250540)

<u>Additional Predicates:</u>

Globus Medical, Hedron IC (K191243)

The subject components are identical in indications to the primary predicate device. Device sizing, geometry, and technological characteristics, and materials are similar to the predicate Hedron IC (K191243). Materials, manufacturing, sterilization, and packaging are identical to those of the primary predicate, Saber-C (K250540).

Performance Testing:

The following bench performance testing has been performed on the subject additively manufactured interbody devices Static and Dynamic Axial Compression, Static and Dynamic Compression Shear, Static and Dynamic Torsion per ASTM F2077, Expulsion, and Subsidence per ASTM F2267

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.