Elevation Spine
% Mr. Steve Brown
QA/RA Manager
CoorsTek Medical
560 West Golf Course Road
Providence, Utah 84332

August 7, 2019

Re: K190885
Trade/Device Name: Elevation Spine Saber-C System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP, KWQ
Dated: July 12, 2019
Received: July 15, 2019

Dear Mr. Brown:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Melissa Hall
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190885

Device Name
Elevation Spine Saber-C System

Indications for Use *(Describe)*

Indications for Use:

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 at a single spinal level. 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. 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.

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.

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510(k) SUMMARY

Device Trade Name:	**Elevation Spine Saber-C System**
Date:	July 12, 2019
Sponsor:	Elevation Spine 2511 Garden Rd. Suite B260 Monterey, CA 93940 (650) 302-7504
Contact Person:	Steve Brown
Manufacturer:	Elevation Spine
Common Name:	Anterior Cervical Integrated Fixation Spacer System
Device Classification:	Class II
Classification Name:	Intervertebral body fusion device, Spinal intervertebral body fixation orthosis
Regulation:	888.3080 888.3060
Device Regulation Panel:	Orthopedic
Device Product Code:	OVE, ODP, KWQ

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the Elevation Spine Saber-C System.

Indications for Use:
Indications for Use:

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 at a single spinal level. 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. 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.

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 SABER-C System is made from radiolucent polymer, 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, spike 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.

Implant Materials

Material:	Standard:
Implant Grade PEEK	ASTM F2026-17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.
Titanium	ASTM F136-13 Standard Specification for Wrought Titanium-6 Aluminum-4 ELI (Extra Low Interstitial) Alloy for Surgical Implant Application (UNS R56401) ASTM F1472-14 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Application (UNS R56400)
Titanium alloy coating	ASTM F1580-18 Standard Specification for Titanium and Titanium-6 Aluminum-4 Alloy Powders for Coating of Surgical Implants

Legally Marketed Predicate Devices:
Globus Coalition AGX (Primary Predicate)
K142218
K173115

Technological Characteristics:
There are no technological characteristics that raise new issues of safety or effectiveness. The Elevation Spine SABER-C is substantially equivalent with respect to its intended use, geometry, materials, and the method of fixation.

Performance Testing:
The SABER-C System Anterior Cervical Integrated Fixation Spacer System was designed and tested as an interbody fusion device for the cervical spine. The objective of this testing was to demonstrate that the subject device is equivalent to predicate devices with respect to testing recommended in ASTM F2077-14 and F2267-11.

Three configurations of the Elevation Spine Saber-C System were tested in static and dynamic axial compression, compression-shear, and torsion per ASTM F2077-14, subsidence per ASTM 2267-11, and expulsion. Additionally, a cadaver implantation study was performed on the plate and spacer assembly when used with spiked fixation.

Conclusion
In summary, the results of the performance testing demonstrate that the Elevation Spine SABER-C is substantially equivalent with respect to its intended use, geometry, materials, and the method of fixation.