



December 5, 2025

Lincotek Medical
% Christine Scifert
Partner
MRC Global
9085 E Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K250764

Trade/Device Name: SpineLinc Anterior Cervical Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: March 12, 2025
Received: March 13, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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

Submission Number (if known)

K250764

Device Name

SpineLinc Anterior Cervical Implant System

Indications for Use (Describe)

The SPINELINC Anterior Cervical Implants include cervical interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two 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 SPINELINC Cervical Spacer Body and Anterior Cervical Spaver are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. The SPINELINC Cervical Spacer Body and Anterior Cervical Spacer are intended to be used with FDA cleared supplemental fixation. Only the SPINELINC Cervical Spacer Body is compatible with the SPINELINC Plates and Screws. When used with the SPINELINC Plate and Screws, the plate-spacer assembly takes on the indications for use of the SPINELINC Cervical Spacer Body, with the SPINELINC Plate and Screws acting as the supplemental fixation. The SPINELINC Plate and Cervical Spacer Body assembly is a stand-alone device intended for use at one or two levels of the cervical spine (C2-T1) and is to be used with three SpineLinc screws per assembly.

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

SpineLinc Anterior Cervical Implant System
November 7, 2025

Company: Lincotek Medical
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Bartlett, TN 38133

Primary Contact: Christine Scifert – Partner
MRC Global
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Company/Secondary Contact: Troy Walters
Director of Product Development
Lincotek Medical
Phone: 574-274-0186
Troy.walters@lincotek.com

Trade Name: SpineLinc Anterior Cervical Implant 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, ODP

Primary Predicate: Globus Medical HEDRON Spacers – K191243

Device Description:

The SpineLinc Anterior Cervical Implant system consists of a cervical interbody fusion device, cervical plate, screws, and a locking clip, which may be implanted in various configurations to accommodate patient anatomy. The SpineLinc Anterior Cervical implant devices are offered manufactured from titanium alloy per ASTM F136 or ASTM F3001. Instrumentation is provided with the SpineLinc Anterior Cervical Implant system to facilitate implantation. Instruments are manufactured from medical grade

stainless steel per ASTM F899. All subject implants and instruments are provided sterile via gamma irradiation and are provided as single use kits.

Indications for Use:

The SPINELINC Anterior Cervical Implants include cervical interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) for one or two 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 SPINELINC Cervical Spacer Body and Anterior Cervical Spaver are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. The SPINELINC Cervical Spacer Body and Anterior Cervical Spacer are intended to be used with FDA cleared supplemental fixation. Only the SPINELINC Cervical Spacer Body is compatible with the SPINELINC Plates and Screws. When used with the SPINELINC Plate and Screws, the plate-spacer assembly takes on the indications for use of the SPINELINC Cervical Spacer Body, with the SPINELINC Plate and Screws acting as the supplemental fixation. The SPINELINC Plate and Cervical Spacer Body assembly is a stand-alone device intended for use at one or two levels of the cervical spine (C2-T1) and is to be used with three SpineLinc screws per assembly.

Substantial Equivalence:

The subject SpineLinc Anterior Cervical Implant system components are substantially equivalent to the following predicate devices:

Primary Predicate:

- Globus Medical HEDRON Cervical Spacers – K191243

Additional Predicates:

- Globus Medical, COALITION AGX™ Plate and COALITION AGX™ Spacer – K142218
- Elevation Spine SABER-C System – K190885

The subject components are similar in indications to the predicate devices. Device sizing, geometry, technological characteristics, and materials are similar to the predicate Hedron Cervical Spacers (K191243) with the COALITION AGX Plate (K142218), and Saber-C (K190885).

Performance Testing:

The following bench performance testing has been conducted on the subject SpineLinc Anterior Cervical Implant system: Static and Dynamic Axial Compression per ASTM F2077, Static and Dynamic Compression Shear per ASTM F2077, Static and Dynamic Torsion per ASTM F2077, Expulsion, and Subsidence per ASTM F2267. MR Compatibility was assessed utilizing simulation of ASTM 2182-19e2 test method.

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.