September 18, 2023

Nexus Spine, LLC
% Christine Scifert
Partner
MRC Global
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K232530
Trade/Device Name: Stable-L Standalone Lumbar Interbody System, Stable-C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, OVE
Dated: August 18, 2023
Received: August 21, 2023

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 (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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232530

Device Name
Stable-L Standalone Lumbar Interbody System

Indications for Use *(Describe)*

The Stable-L Standalone Lumbar Interbody System is indicated for spinal fusion procedures in skeletally mature patients. Stable-L is designed for use with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are to be used in patients who have had at least six months of non-operative treatment. Stable-L is intended for use in interbody fusions in the lumbar spine from L2 to S1 at one or two adjacent levels in the treatment of symptomatic degenerative disc disease (DDD). The DDD patients may also have up to Grade 1 spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation. However, for hyperlordotic devices (> 20° lordosis), due to the increased risk of anterior migration with hyperlordotic implants, the devices should be used with the bone screws provided and supplemental fixation such as posterior 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232530

Device Name
Stable-C Interbody System

Indications for Use *(Describe)*

The Nexus Spine Stable-C Interbody System is an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one level from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Stable-C Interbody System is a standalone system intended to be used with the bone anchors provided. The system is intended to be used with autogenous or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The system is to be used in patients who have had six weeks of non-operative treatment.

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)

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510(k) Summary
Stable-L Standalone Lumbar Interbody System and
Stable-C Interbody System
August 31, 2023

Company: Nexus Spine, LLC
2825 East Cottonwood Parkway Suite 330
Salt Lake City, UT 84121

Primary/Secondary Contact: Christine Scifert – Partner
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Company Contact: Jared Crocker
Vice President of Quality and Regulatory Affairs
Nexus Spine, LLC
Phone: (801) 702-8592
jared.crocker@nexusortho.com

Trade Name: Stable-L Standalone Lumbar Interbody System
Stable-C Interbody System

Common Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar
Intervertebral Fusion Device With Integrated Fixation, Cervical

Classification: Class II

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

Panel: Orthopedic

Product Code: OVD, OVE

Primary Predicate: Nexus Spine, LLC Stable-L Standalone Lumbar Interbody System – K212498

Device Description:

The Stable-L Interbody System is a stand-alone lumbar interbody system including an interbody cage additively manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001 and associated bone screws manufactured from titanium alloy per ASTM F136. The device is offered in a variety of sizes to accommodate patient anatomy. Stable-L Interbody devices are provided nonsterile and are expected to be sterilized by the end-user prior to use.

The Stable-C Interbody System is an anterior cervical interbody device comprised of an interbody cage (lordotic angles of 0 ,°6°, and 12°) made from titanium alloy (Ti-6Al-4V) per ASTM F3001 and two fixation anchors made from titanium alloy (Ti-6-Al-4V ELI) per ASTM F136. The device is offered in a variety of sizes to accommodate patient anatomy.

The purpose of this Special 510(k) submission is to gain clearance for the subject devices to be provided sterile via gamma radiation.

Indications for Use:

The Stable-L Standalone Lumbar Interbody System is indicated for spinal fusion procedures in skeletally mature patients. Stable-L is designed for use with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are to be used in patients who have had at least six months of non-operative treatment. Stable-L is intended for use in interbody fusions in the lumbar spine from L2 to S1 at one or two adjacent levels in the treatment of symptomatic degenerative disc disease (DDD). The DDD patients may also have up to Grade 1 spondylolisthesis at one or two adjacent levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation. However, for hyperlordotic devices (> 20° lordosis), due to the increased risk of anterior migration with hyperlordotic implants, the devices should be used with the bone screws provided and supplemental fixation such as posterior fixation.

The Nexus Spine Stable-C Interbody System is an anterior cervical interbody fusion system indicated for use in skeletally mature patients with cervical disc disease (DDD) at one level from C2-T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Stable-C Interbody System is a stand alone system intended to be used with the bone anchors provided. The system is intended to be used with autogenous or allogenic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. The system is to be used in patients who have had six weeks of non-operative treatment.

Substantial Equivalence:

The subject Nexus Spine Stable-L Standalone Lumbar Interbody System and Stable-C Interbody System are substantially equivalent to the legally marketed predicate devices:

Primary Predicate:

- Nexus Spine, LLC, Stable-L Standalone Lumbar Interbody System –K212498

Secondary Predicate:

- Nexus Spine, LLC, Stable-C Interbody System – K231763

The subject components are identical in indications, sizing and geometry, technological characteristics, and materials to the predicates. The only difference between the subject device and predicate device is that the subject device is provided sterile via gamma radiation and the predicate device is provided non-sterile. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

The is no change to the intended use, indication for use, materials, geometry, or dimensions to the Stable-L Stnadalone Lumbar Interbody System or Stable-C Interbody System. Therefore, there is no mechanical performance testing included in this submission. Sterilization validation, packaging validations, and shelf life validation have all been performed to support the gamma radiation sterilization change.

Conclusion:

The subject device is determined to be substantially equivalent to the predicate devices.