October 12, 2023

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

Re: K231486
Trade/Device Name: Stable-L Standalone Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: September 11, 2023
Received: September 11, 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 (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.

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

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)*
K231486

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.

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510(k) Summary
Stable-L Standalone Lumbar Interbody System
June 30, 2023

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

Primary Contact: Christine Scifert – Partner
MRC Global
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Centennial, CO 80112
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Company/Secondary 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

Common Name: Intervertebral Fusion Device With Integrated Fixation, Lumbar

Classification: Class II

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

Panel: Orthopedic

Product Code: OVD

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

Device Description:

The Stable-L Standalone Lumbar 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 subject submission seeks to gain clearance for design changes to the previously cleared devices, as well as expand the screw offerings of the system.

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.

Substantial Equivalence:

The subject Nexus Spine Stable-L Standalone Lumbar Interbody System is substantially equivalent to the following predicate devices:

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

There are insignificant differences between the subject Stable-L Standalone Interbody System and the predicate. The Indications for Use and Materials of the subject device are identical to those of the predicate. There are slight geometry differences between the subject and predicate devices but overall geometry is the same and confirmatory testing has shown that the subject Stable-L devices perform equivalent to the predicate devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

The following confirmatory bench performance testing was performed on the subject Stable -L Dual Lead (DL) Screws: screw insertion torque. Additional confirmatory static compression and static compression shear was performed on the subject changes to the interbody device. Confirmatory screw pull out testing was also conducted on the cover plates. Testing has confirmed that the proposed design changes do not raise new issues of safety and effectiveness and therefore, the subject device is substantially equivalent to the previously cleared device.

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.