March 18, 2022

Nexus Spine, LLC
Jared Crocker
Vice President of Quality and Regulatory Affairs
2825 East Cottonwood Parkway, Suite 330
Salt Lake City, Utah 84121

Re: K212498
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: February 17, 2022
Received: February 18, 2022

Dear Jared Crocker:

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
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)*
K212498

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

Submitter: Nexus Spine LLC

Contact Person: Mr. Jared Crocker, Vice President of Quality and Regulatory Affairs
2825 East Cottonwood Parkway Suite 330
Salt Lake City, UT 84121
Telephone: (801) 702-8592
Fax: (801) 702-8585

Date Prepared: March 17, 2022

Trade Name: Stable-L Standalone Lumbar Interbody System

Classification, Name and Number: Class II
Intervertebral body fusion device
21 CFR 888.3080

Product Code: OVD

Predicate Device(s):

Manufacturer	Device	510(k) Number
Primary Predicate		
NuVasive, Incorporated	Brigade Standalone System	K203201
Additional Predicates		
Globus Medical	Independence MIS Anterior Lumbar Interbody Fusion System	K203278
Nexus Spine, LLC	Tranquil-L Interbody System	K181702
Synthes USA Products, LLC	SYNFIX Evolution System	K162358
Centinel Spine	STALIF Midline	K101301
Centinel Spine	STALIF TT	K073109
Theken Spine	Vu aPOD	K101310

Device Description: The Stable-L™ Standalone Interbody System is made of Ti-6Al-4V. The implant is offered in various angles, widths, heights, and lengths, and with various lengths of screws, to meet patient anatomy. The devices and instruments are provided clean and non-sterile for steam sterilization at the user's facility.

The purpose of this traditional 510(k) is to gain clearance for this device.

Intended 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.

Statement of Technological Comparison:

The subject spacer system is similar to predicate devices in regard to indications for use, manufacturing process, materials, means of primary and secondary fixation, operating principles, and non-clinical performance standards.

Performance Data:

Mechanical performance testing data was provided as part of this submission to establish substantial equivalence for its use. Static and dynamic compression and compression shear testing per ASTM F2077, screw pushout testing, and implant expulsion testing were performed to establish substantial equivalence.

Conclusion:

Documentation provided demonstrates that the Stable-L Standalone Lumbar Interbody System is substantially equivalent to predicate devices.