August 21, 2023

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

Re: K231763
Trade/Device Name: Stable-C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: June 15, 2023
Received: June 16, 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,

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)*
K231763

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 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.

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-C Interbody System
August 7, 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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Company/Secondary Contact: Jared Crocker
Vice President of Quality and Regulatory Affairs
Nexus Spine, LLC
Phone: (801) 702-8592
jared.crocker@nexusspine.com

Trade Name: Stable-C Interbody 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

Primary Predicate: Nexus Spine, LLC Stable-C Interbody System – K181621

Device Description:

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 integrated fixation anchors may not provide adequate stability for all situations. The Surgeon should consider the appropriate fixation required for each patient and determine if additional supplemental fixation may be needed. When used without the supplied fixation, the Stable-C is intended for use with supplemental fixation (e.g., anterior

plate, posterior pedicle screws). The device is offered in a variety of sizes to accommodate patient anatomy. The devices and instruments are provided clean and non-sterile for steam sterilization at the user's facility.

The subject system seeks to gain clearance for updated indications for use and design changes to the previously cleared device.

Indications for Use:

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-C Interbody System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Nexus Spine, LLC, Stable-C Interbody System – K181621

Secondary Predicate:

- Aesculap ArcadiusXP C Spinal System – K153629
- Genesys Spine AIS-C Cervical Stand-Alone System – K181295

There are insignificant differences between the subject Stable-C Interbody System and the primary predicate (K181621). The Indications for Use for the subject device have been expanded to specify use of the integrated anchors, similar to the predicate Genesys Spine AIS-C Stand Alone System (K181295). The Materials of the subject device are identical to those of the primary predicate. There are slight geometry differences between the subject and predicate devices but testing and cadaveric validation have shown that the subject Stable-C Interbody 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:

Confirmatory bench performance testing was performed on the subject Stable -C interbody devices dynamic axial compression and dynamic axial compression shear per ASTM F2077-18. Additional cadaveric testing was conducted on the subject IBDs. Testing has confirmed that the proposed design changes and change in indications 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.