March 12, 2024

Nexus Spine, LLC
Christine Scifert
MRC Global
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K240416
Trade/Device Name: Tranquil-C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: February 7, 2024
Received: February 12, 2024

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,

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)*
K240416

Device Name
Tranquil-C Interbody System

Indications for Use *(Describe)*
The Tranquil-C™ Interbody System is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 – T1. The Tranquil-C™ Interbody System is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The Tranquil-C™ Interbody System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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.

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510(k) Summary
Tranquil-C Interbody System
February 23, 2024

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

Primary/Secondary Contact: Christine Scifert – Partner
MRC Global
9085 E. Mineral Cir., Suite 110
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Jen McBride – Regulatory Consultant
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Company Contact: Jared Crocker
Vice President of Quality and Regulatory Affairs
Nexus Spine, LLC
Phone: (801) 702-8592
jared.crocker@nexusspine.com

Trade Name: Tranquil-C Interbody System

Common Name: Intervertebral Fusion Device With Bone Graft, Cervical

Classification: Class II

Regulation: 21 CFR 888.3080 (Intervertebral Fusion Device)

Panel: Orthopedic

Product Code: ODP

Primary Predicate: Nexus Spine, LLC Tranquil Interbody System – K181483

Device Description:

The Tranquil-C™ Interbody System is a cervical interbody fusion system. Implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001. The implants are offered in various angles, widths, heights, and lengths to meet patient anatomy for the cervical spine. Implants are provided non-sterile or

sterile via gamma irradiation. Instruments are provided clean and non-sterile for steam sterilization at the user's facility.

The purpose of this special 510(k) is to gain clearance for modifications to existing cervical implants and the size range offered.

Indications for Use:

The Tranquil-C™ Interbody System is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 – T1. The Tranquil-C™ Interbody System is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The Tranquil-C™ Interbody System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Substantial Equivalence:

The subject Nexus Spine Tranquil-C™ Interbody System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Nexus Spine, LLC, Tranquil™ Interbody System – K181483

Additional Predicates:

- Nexus Spine, LLC, Tranquil Interbody System – K170297
- Spinal Elements, Ventana™ C – K222833
- Nexus Spine, LLC – Stable L and Stable C Interbody System – K232530

There are insignificant differences between the subject Tranquil-C™ Interbody System and the predicate Tranquil-C devices (K181483; K170297). Materials and indications of the subject device are identical to those of the predicate devices. There are slight geometry differences between the subject and predicate devices but the extended size range of the subject device falls within the size range of the previously cleared devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Engineering analysis has determined that the subject changes do not create a new worst case condition. Therefore, previously conducted testing remains applicable an no additional performance testing is required.

Conclusion:

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