May 2, 2023

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

Re: K223529
Trade/Device Name: PressON Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: March 30, 2023
Received: March 31, 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,

Colin O'neill -S

Colin O'Neill, M.B.E.
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)*

K223529

Device Name

PressON Spinal Fixation System

Indications for Use *(Describe)*

The PressON Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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
PressON Spinal Fixation System
March 30, 2023

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

Primary Contact: Christine Scifert
Partner, MRC Global
9085 E. Mineral Cir., Suite 110, Centennial, Colorado 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: PressON Spinal Fixation System

Common Name: Thoracolumbosacral pedicle screw system

Classification: Class II

Regulation: 21 CFR 888.3070 - Thoracolumbosacral Pedicle Screw System

Panel: Orthopedic

Product Code: NKB

Primary Predicate: K160820 Nexus Spine, LLC, PressON Pro Spinal Fixation System

Device Description:
The PressON Spinal Fixation System is composed of pedicle screws and rods. These components can be assembled and implanted using associated instruments via a posterior approach into the pedicles of the noncervical vertebral bodies. The system is composed of pedicle screws, cortical screws, and a variety of couplers. All components of the PressON Spinal Fixation System are made from Ti-6Al-4V ELI (ASTM F-136).

Indications for Use:
The PressON Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Substantial Equivalence:
The subject components are substantially equivalent to the following predicate device:
PressON Pro Spinal Fixation System, Nexus Spine, LLC (K160820)

Statement of Technological Comparison:
The PressON Spinal Fixation System is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

Performance Testing:
The following mechanical performance tests were conducted:

ASTM F1717	Dynamic Compression Bending
ASTM F1798	Axial Load Gripping Capacity
ASTM F1798	Axial Torsion Gripping Capacity
ASTM F1798	Flexion-Extension Gripping Capacity
ASTM F1798	Anterior-Posterior Gripping Capacity

Performance testing was performed, and results demonstrated that the subject device is substantially equivalent to the predicate device.

Conclusion:
The subject device, PressON Spinal Fixation System, is substantially equivalent to the PressON Pro Spinal Fixation System, Nexus Spine, LLC (K160820).