February 2, 2023

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

Re: K223627
Trade/Device Name: PreView-III™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 1, 2022
Received: December 5, 2022

Dear Ms. 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)*

K223627

Device Name
PreView-III™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The PreView-III™ Anterior Cervical Plate System is intended for the treatment of the cervical spine in skeletally mature patients receiving fusion by autogenous and/or allogenic bone graft. The implants are attached to the anterior cervical spine (C2-T1). PreView-III™ Anterior Cervical Plate System is intended for use under the following indications degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture), tumor, deformity (i.e., kyphosis, lordosis, and scoliosis), spinal stenosis, pseudoarthrosis, and failed previous 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.

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510(k) Summary
PreView-III™ Anterior Cervical Plate System
January 31, 2023

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

Primary Contact: Christine Scifert
Partner, MRC Global
Phone: (901) 831-8053
Email: christine.scifert@AskMRCGlobal.com

Trade Name: PreView-III™ Anterior Cervical Plate System

Common Name: Appliance, Fixation, Spinal Intervertebral Body

Classification: Class II

Regulation: 21 CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis

Panel: Orthopedic

Product Code: KWQ

Primary Predicate: K062371 PreView Anterior Cervical Plate System, Alphaspine, Inc

Device Description:
The PreView III™ Anterior Cervical Plate System is composed of the following components:

- Plates with preassembled locking rings
- Bone screws

These components can be assembled by associated instruments to provide immobilization of the cervical spine. All components made from Ti-6Al-4V ELI (ASTM F-136).

Indications for Use:
The PreView III™ Anterior Cervical Plate System is intended for the treatment of the cervical spine in skeletally mature patients receiving fusion by autogenous and/or allogenic bone graft. The implants are attached to the anterior cervical spine (C2-T1). The PreView III™ Anterior

Cervical Plate System is intended for use under the following indications degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture), tumor, deformity (i.e., kyphosis, lordosis, and scoliosis), spinal stenosis, pseudoarthrosis, and failed previous fusion.

Substantial Equivalence:
The subject components are substantially equivalent to the following predicate device:

- PreView Anterior Cervical Plate System, Alphaspine, Inc (K062371)

The subject components are substantially equivalent to the primary predicate device listed above in terms of intended use, materials of construction, principles of operation, and general design.

Performance Testing:
The following mechanical performance tests were conducted per ASTM F1717:

- Static Compression Bending
- Static Torsion
- Dynamic Compression Bending

The results demonstrated that the subject device has substantially equivalent mechanical performance to predicate device.

Conclusion:
The data presented in this submission demonstrates that the subject PreView III™ Anterior Cervical Plate System is substantially equivalent to the predicate, Alphaspine, Inc, PreView Anterior Cervical Plate System (K062371).