January 12, 2021

Precision Spine, Inc.
℅ Nathan Wright, MS
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K203129
Trade/Device Name: NexGen Standalone Anterior Cervical Discectomy and Fusion (ACDF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: October 15, 2020
Received: October 19, 2020

Dear Mr. Wright:

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, 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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K203129

Device Name
NexGen Standalone Anterior Cervical Discectomy and Fusion (ACDF) System

Indications for Use *(Describe)*

The NexGen Standalone ACDF System is a standalone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one or two disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The NexGen implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate fusion in the cervical spine. The device is placed via an anterior approach at the C2 to T1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

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.

510(K) SUMMARY

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Drive Pearl, MS 39208
Submitter's Telephone:	1-601-420-4244
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	October 15, 2020
Trade or Proprietary Name:	NexGen Standalone Anterior Cervical Discectomy and Fusion (ACDF) System
Common or Usual Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVE, ODP
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The NexGen Standalone Anterior Cervical Discectomy and Fusion (ACDF) System implants are available in various heights and geometric footprints to accommodate individual patient anatomy and graft material size. NexGen Interbody devices are inserted through an anterior cervical approach and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance, while screws are inserted through the anterior titanium portion of the implant for bone fixation. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

All implantable components are made from medical grade polyetheretherketone (PEEK), tantalum, and titanium or titanium alloy as described by such standards as ASTM F2026, ASTM F560, and ASTM F136/ISO 5832-3. The products are supplied clean and non-sterile.

INDICATIONS FOR USE

The NexGen Standalone ACDF System is a standalone cervical interbody device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one or two disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The NexGen implants are used with two titanium alloy screws and filled with autogenous bone graft material to facilitate fusion in the cervical spine. The device is placed via an anterior approach at the C2 to T1 disc levels. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device.

TECHNOLOGICAL CHARACTERISTICS

The NexGen Standalone ACDF System is made from PEEK per ASTM F2026, tantalum per ASTM F560, and Ti-6Al-4V ELI per ASTM F136/ISO 5832-3. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Sizes and Styles
- Mechanical Strength

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K132029	Vault-C Standalone Cervical Interbody Fusion System	Spinal USA, Inc.	Primary
K173077	Cavetto®-SA Cervical System	Neurostructures, Inc.	Additional
K102606	AVS® Anchor-C Cervical Cage System	Stryker Spine	Additional
K152793	Unison-C Anterior Cervical Fixation System	RTI Surgical	Additional

PERFORMANCE DATA

The NexGen Standalone ACDF System has been tested in the following test modes:

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic compression shear per ASTM F2077
- Static and dynamic torsion per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that NexGen Standalone ACDF System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the NexGen Standalone ACDF System is substantially equivalent to the predicate device.