April 1, 2022

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

Re: K213118
Trade/Device Name: Dakota ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 2, 2022
Received: March 3, 2022

Dear Nathan 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,

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

510(k) Number *(if known)*

Device Name
Dakota ALIF System

Indications for Use *(Describe)*

The Dakota ALIF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The Dakota ALIF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device. The Dakota ALIF System is a stand-alone system intended to be used with the bone screws provided. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system that has been cleared by the FDA for use in the lumbar spine.

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.

K213118 - 510(K) SUMMARY

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Drive Pearl, Mississippi 39208
Submitter's Telephone:	601-420-4244
Contact Person:	Nathan Wright MS Empirical Testing Corp. 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	March 28, 2022
Trade or Proprietary Name:	Dakota ALIF System
Common or Usual Name:	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Dakota ALIF System consists of cages in various widths, heights, and lordoses to accommodate individual patient anatomy and graft material size and bone screws. The devices are intended to provide mechanical support to the implanted level until biologic fusion is achieved. The Dakota ALIF System cages are medical grade PEEK (per ASTM F2026) with tantalum (per ASTM F560) markers and titanium alloy Ti-6Al-4V (per ASTM F136 or ISO 5832-3) integrated fixation screws and screw backout prevention plates. The cages are provided non-sterile.

INDICATIONS FOR USE

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TECHNOLOGICAL CHARACTERISTICS

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

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Product Code**	**Predicate Type**
K173082	Arco™-SA Lumbar Cage System	NeuroStructures, Inc.	OVD	Primary
K130445/K103369	Vault ALIF System	Spinal USA	OVD	Additional
K173347	STALIF M FLX™	Centinel Spine, Inc.	OVD	Additional

PERFORMANCE DATA

The Dakota ALIF 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
- Subsidence per ASTM F2267
- Screw-backout testing

The results of this non-clinical testing show that the strength of the Dakota ALIF 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 Dakota ALIF System is substantially equivalent to the predicate device.