November 24, 2025

Precision Spine Inc.
% Nathan Wright, MS, RAC
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K250769
Trade/Device Name: Dakota LP System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: October 30, 2025
Received: October 30, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250769

Device Name
Dakota LP Anterior Cervical Interbody Fusion System

Indications for Use *(Describe)*
The Dakota LP Anterior Cervical Interbody Fusion System is indicated 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. Dakota LP Anterior Cervical Interbody Fusion System implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device. The device should be used with supplemental fixation.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K250769 - 510(K) SUMMARY

Submitter's Name: Submitter's Address: Submitter's Telephone:	Precision Spine Inc. 2050 Executive Drive Pearl, Mississippi 39208 201-953-0500
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	March 13, 2025
Trade or Proprietary Name:	Dakota LP Anterior Cervical Interbody Fusion System
Device Classification Name:	Intervertebral Fusion Device with Bone Graft, Cervical
Classification & Regulation #:	Class II per 21 CFR 888.3080
Product Code:	ODP
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Dakota LP Anterior Cervical Interbody Fusion System includes cervical interbody fusion spacers to provide mechanical support of the cervical spine until fusion of the treated level occurs. The Dakota LP Anterior Cervical Interbody Fusion System implants are offered in a variety of sizes to accommodate patient anatomical needs and are manufactured from Ti-6Al-4V ELI per ASTM F3001 (cages) and Magnolia PEEK per ASTM F2026 with Tantalum per ASTM F560 (cages) with or without commercially pure titanium coating per ASTM F67.

INDICATIONS FOR USE

The Dakota LP Anterior Cervical Interbody Fusion System is indicated 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. Dakota LP Anterior Cervical Interbody Fusion System implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft bone. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device. The device should be used with supplemental fixation.

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 the same between the subject and predicates:

- Indications for Use
- Structure and Function
- Materials of Manufacture
- Implant Sizes and Styles

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K142218	COALITION AGX™ Plate and COALITION AGX™ Spacer	Globus Medical, Inc.	ODP, OVE, KWQ	Primary
K233509	Zavation IBF System	Zavation Medical Products LLC	MAX, ODP	Additional
K191243	HEDRON™ Cervical Spacers	Globus Medical, Inc.	ODP, OVE	Additional

PERFORMANCE DATA

The Dakota LP Anterior Cervical Interbody Fusion System has been tested in the following test methods:

- 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
- Static tensile strength per ASTM F1147
- Shear fatigue strength per ASTM F1160
- Taber abrasion resistance per ASTM F1978

The results of this non-clinical testing show that the strength of the Dakota LP Anterior Cervical Interbody Fusion 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 LP Anterior Cervical Interbody Fusion System is substantially equivalent to the predicate device.