August 15, 2023

Wenzel Spine, Inc.
℅ Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
Mcra LLC
803 7th Street NW, Third Floor
Washington, District of Columbia 20001

Re: K231807
Trade/Device Name: primaLOK™ SP Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: June 20, 2023
Received: June 20, 2023

Dear Justin Eggleton:

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)*
K231807

Device Name
primaLOK™ SP Interspinous Fusion System

Indications for Use *(Describe)*
The primaLOK™ SP Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), tumor, and/or lumbar spinal stenosis. The primaLOK™ SP Interspinous Fusion System is intended for use with bone graft material and not intended for stand-alone use.

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.

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510(k) Summary

Device Trade Name: primaLOK™ SP Interspinous Fusion System

Manufacturer:
Wenzel Spine, Inc.
1130 Rutherford Ln #200
Austin, TX 78753

Contact:
William Wilson
Chief Executive Officer (CEO)
Wenzel Spine, Inc.
1130 Rutherford Lane, Suite 200
Austin, TX 78753
wwilson@wenzelspine.com

Prepared by:
Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
jeggleton@wenzelspine.com
Office: 202.552.5800

Secondary Correspondent:
Michael Coladonato
Manager, Regulatory Affairs
MCRA, LLC
803 7th Street, NW
Washington, DC 20001
mcoladonato@mcra.com
Office: 202.552.5800

Date Prepared: August 9, 2023

Classifications: 21 CFR §888.3050

Class: II

Product Codes: PEK

Primary Predicate: K213266, LESpine Innovations, Inspan® ScrewLES® Fusion

Additional Predicate: K100354, Wenzel Spine Inc., primaLOK™ SP Interspinous Fusion System

The purpose of this Traditional 510(k) is to expand the Indications for Use to include lumbar spinal stenosis for the primaLOK™ SP Interspinous Fusion System, for commercial distribution within the United States of America.

Indications For Use:
The primaLOK™ SP Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), tumor, and/or lumbar spinal stenosis. The primaLOK™ SP Interspinous Fusion System is intended for use with bone graft material and not intended for stand-alone use.

Device Description:
The primaLOK™ SP Interspinous Fusion System is a bilateral locking plate system intended for fixation to the spinous process for the purpose of achieving supplemental fusion. It is available in various interspinous heights and can accommodate a variety of spinous process widths. The device, as a system, consists of longitudinal member/anchor components (base and polyaxial locking plates) and an interconnection component (connecting post).

Predicate Device:
Wenzel Spine Inc, submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, primaLOK™ SP Interspinous Fusion System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to predicate devices:

Primary Predicate: Inspan ScrewLES Fusion System, LESpine Innovations (K213266)

Additional Predicate: primaLOK™ SP Interspinous Fusion, Wenzel Spine, Inc. (K100354)

Performance Testing Summary:
A variety of clinical data and biomechanical evaluations have been conducted in order to support the substantial equivalence of the primaLOK™ SP System to the predicate devices cited within this Traditional 510(k).

Substantial Equivalence:

It has been determined that the primaLOK™ SP System is substantially equivalent to the predicate devices based upon indications, intended use, technological characteristics, principles of operation, materials, biocompatibility, sterility, shelf-life, and packaging.

Conclusion:
The primaLOK™ SP System is substantially equivalent to the cited predicate devices.