December 8, 2021

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

Re: K212075
Trade/Device Name: ShurFit® Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 8, 2021
Received: November 9, 2021

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212075

Device Name

ShurFit® Lumbar Interbody System

Indications for Use *(Describe)*

The ShurFit Lumbar Interbody 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 for the ALIF, LLIF, TLIF and T-PLIF system. Two devices are used per intervertebral space for the PLIF system.

The ShurFit Lumbar Interbody System (ALIF, LLIF, TLIF, T-PLIF and PLIF Systems) 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 supplemental fixation and autogenous autograft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar 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.

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510(K) SUMMARY

Submitter's Name:	Precision Spine, Inc.
Submitter's Address:	2050 Executive Dr. Pearl, MS 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:	July 1, 2021
Trade or Proprietary Name:	ShurFit® Lumbar Interbody System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ShurFit® Lumbar Interbody System consists of implants with various widths, heights, and lengths to accommodate individual patient anatomy and graft material size. The ShurFit® Lumbar Interbody System implants are offered as PLIF (straight), T-PLIF (oblique), TLIF (curved), ALIF, and LLIF. The implants are to be packed with autogenous bone graft to facilitate fusion. The devices are intended to provide mechanical support to the implanted level until biologic fusion is achieved. All components are manufactured either from additive Ti-6Al-4V ELI per ASTM F3001 or from medical grade polyetheretherketone (PEEK Optima, LT1) per ASTM F2026 with or without a coating of Commercially Pure Titanium per ASTM F1580 and Hydroxyapatite per ASTM F1185. PEEK implants contain tantalum markers per ASTM F560. The PEEK implants are provided non-sterile with sterilization instructions; the titanium alloy and the PEEK coated implants are provided sterile.

INDICATIONS FOR USE

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autogenous autograft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

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
- Technological characteristics
- Materials of manufacture
- Range of Sizes

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K171657	ShurFit 2C Lumbar Interbody Fusion System	Precision Spine, Inc.	MAX	Primary
K092193, K081196, K080314	Spinal USA Intervertebral Body Fusion Device	Spinal USA (now Precision Spine, Inc.)	MAX	Additional
K172341	NuVasive® Modulus TLIF Interbody System	NuVasive, Inc.	MAX	Additional
K181589	Curiteva Lumbar Interbody System	Curiteva, LLC	MAX	Additional
K162496	Foundation™ 3D Interbody	CoreLink, LLC	MAX	Additional
K180963	ROCCIA TLIF	Silony Medical GmbH	MAX, PHM	Additional
K201024	Expandable Titanium PLIF/TLIF System	Spectrum Spine, LLC	MAX	Additional

PERFORMANCE DATA

The ShurFit® Lumbar Interbody System Implants have 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

The results of this non-clinical testing show that the strength of the ShurFit® Lumbar Interbody System Implants 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 ShurFit® Lumbar Interbody System Implants are substantially equivalent to the predicate devices.