



Food and Drug Administration
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Precision Spine, Inc.
Mr. Michael C. Dawson
Sr. Director of Regulatory Affairs /
Deputy General Counsel
2050 Executive Drive
Pearl, Mississippi 39208

August 11, 2017

Re: K171657
Trade/Device Name: ShurFit 2C Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 15, 2017
Received: June 5, 2017

Dear Mr. Dawson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K171657

Device Name
ShurFit 2C Lumbar Interbody Fusion System

Indications for Use (Describe)

The ShurFit 2C Interbody Fusion Devices (LLIF and TLIF) are indicated for intervertebral body fusion of the spine in skeletally mature patients. The device is designed to be used with autograft to facilitate fusion. One device is used per intervertebral space for the LLIF and TLIF.

The ShurFit 2C Interbody Fusion Devices (LLIF and TLIF) are intended for use at either one level or two contiguous levels in the lumbar spine, for 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 Drive Pearl, MS 39208
Submitter's Telephone:	973-455-7150 ext. 128
Contact Person:	Michael C. Dawson
Date Summary was Prepared:	August 9, 2017
Trade or Proprietary Name:	ShurFit 2C Lumbar Interbody Fusion System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	87 Orthopedic Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ShurFit 2C Interbody Fusion System (LLIF and TLIF) consists of implants with various widths, heights, and lengths to accommodate individual patient anatomy and graft material size. It is to be packed with autogenous bone graft to facilitate fusion. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved. All components are manufactured from medical grade polyetheretherketone (PEEK Optima, LT1), and coated with Commercially Pure Titanium in compliance with ASTM F1580, and Hydroxyapatite in compliance with ASTM F1185-03. The products are supplied clean and "STERILE". The cages are included without a coating (already cleared K092193) or with a Cp Ti-HA (Commercially Pure Titanium - Hydroxyapatite) coating (this submission).

CHANGE FROM PREDICATE:

The purpose of this submission is to add CpTi-HA (Commercially Pure Titanium - Hydroxyapatite) coated cages to the ShurFit Interbody Fusion System cleared in K092193. This submission seeks to add a line of ShurFit Lumbar devices (LLIF and TLIF) that have a coating on their endplates. The coating consists of a commercially pure Titanium (CpTi) based layer with a Hydroxyapatite (HA) layer on top of the CpTi. Precision Spine relies on the Master File of its contract manufacturer, APS Biomaterials Inc. located at 4011 Riverside Drive, Dayton, Ohio, for the composition and other technical characteristics of the HA and the CpTi coating. A copy of the

MAF authorization letter from APS is attached in Appendix A. The coated products will be supplied sterile in validated sterile packaging.

INDICATIONS FOR USE

The ShurFit 2C Interbody Fusion Devices (LLIF and TLIF) are indicated for intervertebral body fusion of the spine in skeletally mature patients. The device is designed to be used with autograft to facilitate fusion. One device is used per intervertebral space for the LLIF and TLIF.

The ShurFit 2C Interbody Fusion Devices (LLIF and TLIF) are intended for use at either one level or two contiguous levels in the lumbar spine, for 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.

TECHNOLOGICAL CHARACTERISTICS

The intended use and technological features of the modifications/additions to the components of the ShurFit Lumbar Interbody Fusion System do not substantially differ from the legally marketed predicate devices.

All ShurFit 2C Interbody Fusion System components are manufactured from medical grade polyetheretherketone as described by ASTM F2026, specifically PEEK Optima LT1. The coated implants are provided sterile. The subject and predicate devices have identical technological characteristics and differ only in the fact that a CpTi-HA coating has been added and the coated devices will be provided supplied sterile. Additional predicates that contain CpTi-HA coating as well as CpTi or HA are listed below.

Table 1 Predicate Devices

<i>510k Number</i>	<i>Trade or Proprietary or Model Name</i>	<i>Manufacturer</i>
K092193	Spinal USA Interbody Fusion Device	Precision Spine (Spinal USA)
K161809 (Primary Predicate)	ShurFit CpTi-HA ACIF Interbody Fusion System (Coating Predicate)	Precision Spine
K150061	Lucent Ti Bond Systems	Spinal Elements
K133967	Aurora Spine Interbody Fusion System	Aurora Spine
K150321	EVOS HA Lumbar Interbody System	Cutting Edge Spine

The following is a brief summary of non-clinical tests provided to the agency for review:

Mechanical performance of the ShurFit 2C Interbody Fusion System (LLIF and TLIF) was evaluated under the standards of ASTM F2077-11, F2267-04, and the draft standard F-04.25.02.02. The following properties were tested:

- Static Axial Compression
- Dynamic Axial Compression
- Static Compression Shear
- Dynamic Compression Shear
- Static Expulsion
- Static Subsidence

Coating properties were evaluated using the standards ASTM 1147, ASTM F1044, ASTM F1160, and ASTM F1854. The following properties were tested:

- Static Tensile Bond Strength
- Static Shear Strength
- Shear Fatigue
- Solubility and Dissolution
- Microstructural and Image Analysis of coated surface

Additional information on both the CpTi and the HA coatings can be found in the Master Access File of the coatings vendor, APS Materials, attached in Appendix A as well as Coating Characterization reports in Appendix B.

CONCLUSION

The overall technology characteristics and mechanical engineering analysis lead to the conclusion that the ShurFit 2C Interbody Fusion System (LLIF and TLIF) is substantially equivalent to the predicate devices.