DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 6, 2016

Precision Spine, Inc.
Michael C. Dawson, Esq.
Sr. Director of Regulatory Affairs
2050 Executive Drive
Pearl, Mississippi 39208

Re: K161809
Trade/Device Name: ShurFit CpTi-HA ACIF Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 16, 2016
Received: November 21, 2016

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,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K161809

Device Name
ShurFit CpTi-HA ACIF Interbody Fusion System

Indications for Use *(Describe)*

The ShurFit CpTi-HA Coated Anterior Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. ShurFit Anterior Cervical Interbody Fusion System implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 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.

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:	June 22, 2016
Trade or Proprietary Name:	ShurFit CpTi-HA ACIF Interbody Fusion System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	87 Orthopedic Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ShurFit Anterior Cervical Interbody Fusion (ACIF) System consists of implants with various widths, heights and lengths to accommodate individual patient anatomy and graft material size. It is implanted from the anterior approach and 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 as described by ASTM F2026, specifically PEEK Optima LT1. The cages are included without a coating (already cleared K083118) or with a CpTi-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 ACIF Interbody Fusion System cleared in K083118. This submission seeks to add a line of ShurFit ACIF devices 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 of 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. The coated products will be supplied sterile in validated sterile packaging.

INDICATIONS FOR USE

The ShurFit CpTi-HA Coated Anterior Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc

level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. ShurFit Anterior Cervical Interbody Fusion System implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 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 intended use and technological features of the modifications/additions to the components of the ShurFit Anterior Cervical Interbody Fusion System do not substantially differ from the legally marketed predicate devices.

All ShurFit CpTi-HA ACIF 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 or HA are listed below.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Primary or Additional**
K083118	Interbody Fusion Device ACIF System	Precision Spine (Spinal USA)	Primary
K142269	Reliance HA Infused Cervical IBF	Reliance Medical Systems	Additional
K142026	Arena-C HA infused Cervical cage	Spine Frontier	Additional
K112036	Calix PC Titanium coated Cervical cage	X Spine	Additional
K123909	CeSpace Titanium coated Cervical cage	Aesculap	Additional

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

Mechanical performance of the CpTi-HA coated ShurFit® ACIF System 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 Torsion
- Dynamic Torsion
- 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.

CONCLUSION

The overall technology characteristics and mechanical engineering analysis lead to the conclusion that the ShurFit CpTi-HA ACIF Interbody Fusion System is substantially equivalent to the predicate devices.