DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 8, 2016

Orthofix, Inc.
Ms. Natalia Volosen
Senior Regulatory Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K161129
Trade/Device Name: PILLAR® SA PTC
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: August 8, 2016
Received: August 9, 2016

Dear Ms. Volosen:

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 Parts 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" (21CFR 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

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 below.

510(k) Number: K161129

Device Name
PILLAR® SA PTC

Indications for Use *(Describe)*

The PILLAR SA PTC is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s). The PILLAR SA PTC is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The PILLAR SA PTC is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental fixation must be used to augment stability. As an example, the supplemental fixation system that may be used is the Firebird Spinal Fixation System.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLAR SA PTC.

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

PILLAR® SA PTC

510(k) Owner Information

Name:	Orthofix Inc.
Address:	3451 Plano Parkway Lewisville, TX 75056
Telephone Number:	214-937-2145
Fax Number:	214-937-3322
Email:	nataliavolosen@orthofix.com
Registration Number:	2183449
Contact Person:	Natalia Volosen Senior Regulatory Affairs Specialist

Date Prepared:	June 28, 2016

Name of Device

Trade Name / Proprietary Name:	PILLAR® SA PTC
Common Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Product Code:	OVD
Regulatory Classification:	21 CFR § 888.3080
Review Panel:	Orthopedic Device Panel
Predicate Devices:	(K152475) – FORZA PTC Spacer System, Orthofix (primary predicate) (K150643) – STALIF MIDLINE II-Ti, Centinel Spine (additional predicate) (K081849) – PILLAR SA PEEK Spacer System Orthofix (additional predicate) (K121649) – CONSTRUX Mini PEEK Ti Spacer System, Orthofix (reference device)

Reason for 510(k) Submission: New product offering

Device Description

The PILLAR SA PTC in a standalone intervertebral body implant that is comprised of a PEEK OPTIMA LT1 core material as described by ASTM F-2026, with two integrated porous titanium

alloy (Ti-6Al-4V) endplates as described by ASTM F1580 or ASTM F136. The PILLAR SA PTC device is implanted in the intervertebral disc space and is intended to facilitate vertebral fusion by stabilizing adjacent vertebrae, maintaining disc height, and preventing the collapsing of one vertebrate onto another.

The PILLAR SA PTC is designed to be used as a standalone device, when implanted with accompanying stabilizing screws. The PILLAR SA PTC spacers are provided sterile.

Intended Use / Indications for Use

The PILLAR SA PTC is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s). The PILLAR SA PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The PILLAR SA PTC is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental fixation must be used to augment stability. As an example, the supplemental fixation system that may be used is the Firebird Spinal Fixation System.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLAR SA PTC.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices

The technological characteristics of the PILLAR SA PTC are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the PILLAR SA PTC and the predicate devices which would adversely affect the use of the product.

Performance Data – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

The performance of PILLAR SA PTC was assessed for the following: axial compression (ASTM F2077), compression-shear (ASTM F2077), expulsion (draft standard 04.25.05.02), subsidence (ASTM F2267), tensile strength (ASTM F1147), shear (ASTM F1044 & ASTM F1160), wear (ASTM F1877) and TABER abrasion (ASTM F1978). PILLAR SA PTC also underwent characterization of the porous titanium (ASTM F1854) endplates and interface. In addition, bacterial endotoxin testing (BET) has been performed. BET as specified in ANSI/AAMI ST-72:2011 confirm an endotoxin limit less than 20EU per device.

Test results demonstrated that PILLAR SA PTC is substantially equivalent to the predicate devices FORZA PTC Spacer System (K152475), PILLAR SA PEEK Spacer System (K081849), and Stalif Midline II Ti (K150643).

Basis of Substantial Equivalence

The new PILLAR SA PTC has the same intended use and similar indications for use as the Stalif Midline II Ti (K150643) and FORZA PTC Spacer System (K15475), similar technological characteristics and design as the FORZA PTC Spacer System (K152475), PILLAR SA PEEK Spacer System (K081849), and Stalif Midline II Ti (K150643), same or similar materials as the FORZA PTC Spacer System (K152475) and the same principles of operation as FORZA PTC Spacer System (K152475), PILLAR SA PEEK Spacer System (K081849), and Stalif Midline II Ti (K150643).