Orthofix Inc.
Ms. Natalia Volosen
Regulatory Affairs Principal
3451 Plano Parkway
Lewisville, Texas 75056

November 2, 2017

Re: K172437
Trade/Device Name: CONSTRUX® Mini PTC Spacer System, FORZA® PTC Spacer System, PILLAR® SA PTC Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, OVD
Dated: October 10, 2017
Received: October 11, 2017

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 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 (DICE) 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 (DICE) 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 *(if known)*

K172437

Device Name
CONSTRUX® Mini PTC Spacer System
FORZA® PTC Spacer System
PILLAR® SA PTC Spacer System

Indications for Use *(Describe)*

CONSTRUX Mini PTC Spacer System

The CONSTRUX Mini PTC Spacer System is indicated for spinal fusion procedures at one or two contiguous levels within the cervical spine (C2-T1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The CONSTRUX Mini PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation system (i.e., an anterior cervical plate such as the Orthofix Hallmark Anterior Cervical Plate System).

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PTC Spacer System in the cervical spine.

FORZA PTC Spacer System

The FORZA PTC Spacer System 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 levels.

The FORZA Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, e.g., the Firebird Spinal Fixation System.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the FORZA PTC Spacer System.

PILLAR SA PTC Spacer System

The PILLAR SA PTC Spacer System 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 Spacer System is intended for use with four of the titanium alloy screws provided with the system. 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, a supplemental fixation system that may be used is the Orthofix Firebird® Spinal Fixation System.

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

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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ORTHOFIX



## 510(k) SUMMARY

## CONSTRUX® Mini PTC Spacer System, FORZA® PTC Spacer System PILLAR® SA PTC Spacer System

**510(k) Owner Information**


| | |
|---|---|
| Name: | Orthofix Inc. |
| Address: | 3451 Plano Parkway<br>Lewisville, TX 75056 |
| Telephone Number: | 214-937-2145 |
| Fax Number: | 214-937-3322 |
| Email: | nataliavolosen@orthofix.com |
| Registration Number: | 2183449 |
| Contact Person: | Natalia Volosen<br>Regulatory Affairs Principal |
| Date Prepared: | October 10, 2017 |


**Name of Device**

| | |
|---|---|
| Trade Name / Proprietary Name: | CONSTRUX Mini PTC Spacer System<br>FORZA PTC Spacer System<br>PILLAR SA PTC Spacer System |
| Common Name: | Intervertebral body fusion device |
| Product Code: | ODP, MAX, OVD |
| Regulatory Classification: | Class II – 21 CFR § 888.3080 – Intervertebral body fusion device |
| Review Panel: | Orthopedic Device Panel |
| Predicate Devices:<br>Additional Predicate Devices | K161129 – PILLAR SA PTC, SE 9/8/2016<br>K152475 – FORZA PTC Spacer System, SE 1/14/2016<br>K150619 – CONSTRUX Mini PEEK Ti Spacer System, SE 11/29/2012 |

Reason for 510(k) Submission: Manufacturing / Product Description Change

**Device Description**

CONSTRUX Mini PTC Spacer System

The CONSTRUX Mini PTC Spacer System is comprised of a variety of implants that has a PEEK core (conforming to ASTM F2026) with integrated porous Titanium alloy (Ti-6Al-4V) endplates (conforming to ASTM F1580). The implant superior and inferior Titanium plate surface provides increased stability for the implant. The CONSTRUX Mini PTC spacer is implanted in the cervical 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 CONSTRUX Mini PTC Spacer System is not intended to be used as a standalone device. The CONSTRUX Mini PTC Spacer System must be used with a supplemental fixation system. The CONSTRUX Mini PTC Spacer System implants are provided sterile.

FORZA PTC Spacer System

The FORZA PTC Spacer System is comprised of a variety of implants that have a PEEK core (conforming to ASTM F2026) with two integrated porous Titanium alloy (Ti-6Al-4V) endplates (conforming to ASTM F1580). The implant superior and inferior Titanium plate surface provides increased stability for the implant. The FORZA PTC Spacer System 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 FORZA PTC Spacer System is not intended to be used as a standalone device. The FORZA PTC Spacer System must be used with a supplemental fixation system. The FORZA PTC Spacer System implants are provided sterile.

PILLAR SA PTC Spacer System

The PILLAR SA PTC is a standalone intervertebral body implant that is comprised of a PEEK core (conforming to ASTM F2026) with integrated porous Titanium alloy (Ti-6Al-4V) endplates (conforming to ASTM F1580). The implant superior and inferior Titanium plate surface provides increased stability for the implant. 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**

CONSTRUX Mini PTC Spacer System

The CONSTRUX Mini PTC Spacer System is indicated for spinal fusion procedures at one or two contiguous levels within the cervical spine (C2-T1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The CONSTRUX Mini PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation system (i.e., an anterior cervical plate such as the Orthofix Hallmark Anterior Cervical Plate System).

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PTC Spacer System in the cervical spine.

FORZA PTC Spacer System

The FORZA PTC Spacer System 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 levels.

The FORZA Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, e.g., the Firebird Spinal Fixation System.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the FORZA PTC Spacer System.

PILLAR SA PTC Spacer System

The PILLAR SA PTC Spacer System 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 Spacer System is intended for use with four of the titanium alloy screws provided with the system. 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, a supplemental fixation system that may be used is the Orthofix Firebird® Spinal Fixation System.

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

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

The technological characteristics of the CONSTRUX Mini PTC Spacer System, FORZA PTC Spacer System, PILLAR SA PTC Spacer System are similar to the predicate devices in terms of design, size, intended use, materials, and performance characteristics.

**PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence**

Based on manufacturing change and risk assessment the mechanical tests performed are Static and Dynamic Axial Compression Test, Static and Dynamic Compression Shear Test and Static and Dynamic Torsion Test in accordance to ASTM F2077-14 standard for Test Method for Intervertebral Body Fusion Devices.

**Basis of Substantial Equivalence**

CONSTRUX Mini PTC Spacer System, FORZA PTC Spacer System, PILLAR SA PTC Spacer System have the same intended use, indications for use, technological characteristics, materials, the same principles of operation and same design as the predicate device CONSTRUX Mini PEEK Ti Spacer System (K150619), FORZA PTC Spacer System (K152475), and PILLAR SA PTC (K161129).