



April 9, 2020

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

Re: K200052

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: OVD, MAX, ODP

Dated: January 9, 2020

Received: January 10, 2020

Dear Natalia 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. 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,

for
Brent Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K200052
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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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510(k) Summary

Device Trade Name: CONSTRUX Mini PTC Spacer System
FORZA PTC Spacer System
PILLAR SA PTC Spacer System

Manufacturer: Orthofix Inc.
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Lewisville, TX 75056, USA
Phone: (214) 937-2145
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Contact Person: Ms. Natalia Volosen
Regulatory Affairs Principal
nataliavolosen@orthofix.com

Date Prepared: April 9, 2020

Registration Number: 2183449

Product Code: ODP, MAX, OVD

Classifications: Class II – 21 CFR §888.3080, Intervertebral body fusion device

Primary Predicate: K172437 – PILLAR SA PTC, SE 11/2/2017

Additional Predicate Devices: K172437 – FORZA PTC Spacer System, SE 11/2/2017
K172437 – CONSTRUX Mini PTC Spacer System, SE 11/2/2017

Reason for the 510(k) Submission: This 510(k) submission was submitted to add nano-scale descriptors to the labeling in accordance with the FDA Guidance Document “Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology.” Orthofix PTC product demonstrates the requirements for nanotechnology. The PTC surface has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties.

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 titanium endplates have open macroscopic 3D pores with a microscopic roughened surface and nano-scale features. 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 vertebra 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 titanium endplates have open macroscopic 3D pores with a microscopic roughened surface and nano-scale features. 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 vertebra 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 titanium endplates have open macroscopic 3D pores with a microscopic roughened surface and nano-scale features. 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 vertebra 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.

Indications for Use and Intended 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.

Performance Testing Summary:

No new mechanical testing was performed for the CONSTRUX Mini PTC Spacer System, FORZA PTC Spacer System, PILLAR SA PTC Spacer System because there were no design changes to the device.

PTC nano-surface descriptors are supported by surface characterization and in vitro cellular studies using HMSCs and normal human osteoblasts (NH0st) cells. The in vitro study results demonstrated that the PTC modified surface experienced an increased

proliferation and alkaline phosphatase activity (an early osteogenic differentiation marker) in human stem cells compared to the other surfaces.

Substantial Equivalence:

The subject devices are substantially equivalent to the primary predicate, the Orthofix PILLAR SA PTC Spacer System (K172437), and the additional reference devices, with respect to indications, design, materials, function, and performance.

Conclusion:

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 PTC Spacer System, FORZA PTC Spacer System, and PILLAR SA PTC (K172437).