



Food and Drug Administration
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Orthofix Incorporated
Ms. Natalia Volosen
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

January 14, 2016

Re: K152475
Trade/Device Name: FORZA® PTC Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 15, 2015
Received: December 17, 2015

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 yours,

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)

K152475

Device Name

FORZA® PTC Spacer System

Indications for Use (Describe)

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 I spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

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

FORZA® PTC Spacer System

510(k) Owner Information

Name: Orthofix Inc.
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Registration Number: 3008524126

Contact Person: Natalia Volosen
Senior Regulatory Affairs Specialist

Date Prepared: January 13, 2016

Name of Device

Trade Name / Proprietary Name: FORZA® PTC Spacer System

Common Name: Intervertebral body fusion device

Product Code: MAX

Regulatory Classification: Class II per 21 CFR § 888.3080

Review Panel: Orthopedic Device Panel

Predicate Devices: K103111 – FORZA Spacer System, SE 03/23/2011, Orthofix (primary predicate)
K141953 – Endoskeleton TO/TT, SE 10/27/2014, Titan Spine (additional predicate)
K150643 – STALIF MIDLINE II-Ti, SE 06/08/2015, Centinel Spine (additional predicate)
Reference devices – CONSTRUX Mini PEEK Ti Spacer System K121649

Reason for 510(k) Submission: New product offering

Device Description

The FORZA® PTC Spacer System is comprised of a variety of implants that have a PEEK core as described by ASTM F-2026 with two integrated porous Titanium alloy (Ti-6Al-4V) endplates as described by ASTM F1580. 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.

Intended Use / Indications for Use

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 I spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

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

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

The technological characteristics of the FORZA® PTC Spacer system are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics.

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

Mechanical test and analysis was performed to establish mechanical strength for FORZA® PTC Spacer system (Static and Dynamic Axial Compression Test (ASTM F2077-11), Static and Dynamic Compression Shear Test (ASTM F2077-11), Static Torsion Test (ASTM F2077-11), Subsidence Test (ASTM F2267-04) and Expulsion Test (draft ASTM F04.25.02.02). Test results demonstrated that FORZA® PTC Spacer System is substantially equivalent to the predicate FORZA Spacer System K103111.

Surface specific characterization and integrity testing were done per ASTM F1978 (Taber abrasion), ASTM F1147 (tensile testing), ASTM F1044 (coating shear strength) and ASTM F1877 (wear test).

Conclusion

Based upon similarities in design, materials, intended use, indications for use and the results of mechanical testing, the FORZA® PTC Spacer system is substantially equivalent to the predicate devices.