January 19, 2018
Orthofix Inc.
Natalia Volosen
Regulatory Affairs Principal
3451 Plano Parkway
Lewisville, Texas 75056

Re: K172696
Trade/Device Name: FORZA® XP Expandable Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 21, 2017
Received: December 22, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

510(k) Number (if known)
K172696

Device Name
FORZA® XP Expandable Spacer System

Indications for Use (Describe)
FORZA XP Expandable 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).

FORZA XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation (i.e. Firebird® Spinal Fixation System).

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with FORZA XP Expandable 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

FORZA® XP Expandable Spacer System

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
              Regulatory Affairs Principal
Date Prepared: December 13, 2017

Name of Device
Trade Name / Proprietary Name: FORZA XP Expandable Spacer System

Common Name: Intervertebral body fusion device
Product Code: MAX – Intervertebral Fusion Device with Bone Graft, Lumbar
Regulatory Classification: Class II – 21 CFR § 888.3080 – Intervertebral body fusion device
Review Panel: Orthopedic Device Panel

Predicate Devices:
K162918 – Atlas Spine Expandable Interbody System, SE 2/9/2017 (primary predicate)
K150822 – Centurion POCT System, SE 5/15/2015 (reference device)
K140709 – SKYHAWK Interbody Fusion System, SE 5/27/2014 (reference device)
K140260 – SKYHAWK Lateral Plate System, SE 7/02/2014 (reference device)

Reason for 510(k) Submission: Design Change
Device Description
The FORZA XP Expandable Spacer System consists of various size and style options to address the clinical and anatomic needs of individual patients. The implant is rectangular in its general shape with the capability to expand in height continuously within its design limitations. The implant incorporates bone graft cavities through the superior and inferior surfaces to allow fusion between adjacent vertebral bodies. The implant incorporates a posterior opening to allow the addition of bone graft material post expansion. The implants are manufactured from implantable grade Ti6Al4V alloy and PEEK Optima LT1. The implants are delivered pre-assembled, unexpanded and are designed with textured bone contacting surface to resist migration/expulsion post operatively.

Intended Use / Indications for Use
FORZA XP Expandable 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).

FORZA XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation (i.e. Firebird® Spinal Fixation System).

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

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices
The technological characteristics of the modified FORZA XP Expandable 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 design change and risk assessment the mechanical tests performed were Static and Dynamic Axial Compression Tests and Static and Dynamic Compression Shear Tests in accordance to the ASTM F2077-14 standard for Test Method for Intervertebral Body Fusion Devices.

Conclusion
FORZA XP Expandable Spacer System has the same intended use, indications for use, technological characteristics, materials, the same principles of operation and similar design as the predicate devices.