January 5, 2022

Orthofix US LLC
Natalia Volosen
Regulatory Affairs Program Manager
3451 Plano Parkway
Lewisville, Texas 75056

Re: K213951
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 16, 2021
Received: December 17, 2021

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. 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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K213951

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.

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

Device Trade Name: FORZA XP Expandable Spacer System

Manufacturer: Orthofix US LLC
3451 Plano Parkway
Lewisville, TX 75056, USA
Phone: (214) 937-2145
Fax: (214) 937-3322

Contact Person: Ms. Natalia Volosen
Regulatory Affairs Program Manager
nataliavolosen@orthofix.com

Date Prepared: December 16, 2021

Registration Number: 2183449

Product Code: MAX

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

Primary Predicate: K211704 – FORZA XP Spacer System, SE 8/31/2021

Reason for the 510(k) Submission: Product Line Extension

Device Description:
The FORZA XP Expandable Spacer System is comprised of an assortment of single use spacers made from titanium alloy and PEEK Polymer with height expansion capability. The implants feature a bulleted nose for ease of insertion and anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

The implants are offered in non-lordotic, lordotic, and hyperlordotic configurations to help restore the natural curvature of the spine. The implants can be used in single placement or pairs with typical approaches being transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF).

The FORZA XP Expandable Spacer System is not intended to be used as a stand-alone device and must be used with a supplemental fixation system.

Indications for Use and Intended 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.

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.

Performance Testing Summary:

No new mechanical testing was performed for the FORZA XP Expandable Spacer System because there were no design changes to the device.

The proposed sterile package offering does not change the design, materials, function, performance for the FORZA XP implants most recently cleared thru 510(k) K211704. FORZA XP sterile packaging configuration use Orthofix standard sterile packaging configuration recently cleared thru FORZA Ti Spacer System (K211704).

Substantial Equivalence:

The proposed sterile package offering does not change the design, materials, function, performance, indications for use of the device; does not alter the intended use of the implants therefore the subject FORZA XP Expandable sterile packaged devices is substantially equivalent to the FORZA XP Expandable Spacer System (K211704) predicate device

Conclusion:

FORZA XP Expandable Spacer System has the same intended use, indications for use, technological characteristics, materials, the same principles of operation and same design as the predicate device FORZA XP Expandable Spacer System (K211704).