510(k) SUMMARY

Orthofix Inc. FORZA Spacer System

MAR 2 3 2011

Submitter Information

Name:	Orthofix Inc.
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Registration Number:	3008524126
Contact Person:	Darla Chew Director of Regulatory Affairs
Date Prepared:	March 21, 2011

Name of Device

Trade Name / Proprietary Name:	FORZA™ Spacer System
Common Name:	Intervertebral Body Fusion Device
Product Code:	MAX – Intervertebral Fusion Device with Bone Graft, Lumbar
Regulatory Classification:	Class II – 888.3080 – Intervertebral Body Fusion Device
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Blackstone, PILLAR Spacer System, K081177, SE 7-23-08 DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP Spine System: P960025 (i.e., Brantigan Cage) Abbott, Ardis Spacer, K073202, SE 1-30-2008 Advance Medical Technology, Distractable Wave Cage, K083626, SE10-19-2009

Reason for 510(k) Submission: New product offering

Device Description

The FORZA Spacer System consists of implants, trials, and instruments. The FORZA Spacer System is comprised of a variety of implants fabricated and manufactured from polyetheretherketone (PEEK) as described by ASTM F-2026 with Tantalum markers as described by ASTM F-560. PEEK was utilized due to its radiolucent properties, which aids the surgeon in determining if fusion in the operative site has occurred. Since PEEK is transparent in x-rays, Tantalum marker pins are inserted into the implants in order to give surgeons a visual aid in determining the location of the implants, both intra and postoperatively. The implants are offered in two geometric shapes: straight and curved, and offered in lordotic profiles to restore the natural curvature of the spine. Both the curved and straight 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 FORZA Spacer System is intended for intervertebral body fusion to aid in the surgical correction and stabilization of the spine.

The FORZA Spacer System is not intended to be used as a stand-alone device. The FORZA Spacer System must be used with supplemental fixation system. The FORZA Spacer System implants are provided sterile. The FORZA™ Spacer System trials and instruments are provided non-sterile.

Intended Use / Indications for Use

The FORZA™ 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 FORZA™ Spacer System is intended for use with autograft and supplemental fixation system. As an example, the supplemental fixation system that may be used is the Orthofix / Blackstone Medical, Inc. Firebird™ Pedicle Screw System.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the FORZA™ Spacer System.

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

Characteristic	FORZA™ Spacer System (*Under Review*)		Orthofix Inc., PILLAR Spacer System (K081177)		DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP Spine System: P960025	
Function / Design	Restore Biomechanical integrity of the spinal column by providing fusion at one or two contiguous levels in the lumbar spine (L2-S1). The device is intended to be used with autograft material and supplemental fixation system.		Restore Biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device is intended to be used with bone graft material.		The Lumbar I/F Cage device indicated for an open posterior approach using autogenous bone graft at one or two spinal levels from L2-S1 whose condition requires the use of interbody fusion combined with posterolateral fusion and posterior pedicle screw fixation.	
Implant Size(s)	Width	9 – 11mm	Width	9 – 11mm	Width	9 – 15mm
	Length	23 – 33mm	Length	23 – 33mm	Length	21 – 25mm
Implant Heights	6 – 16mm		6 – 16mm		9 – 17mm	
Lordotic Angles	0, 4 and 8°		0 and 8°		Parallel and Wedged	
Configuration	Hollow Cage for use with supplemental fixation		Hollow Cage for use with supplemental fixation		Hollow Cage for use with supplemental fixation	
Material	Polyetheretherketone (PEEK, ASTM F-2026) Tantalum marker (ASTM F-560)		Polyetheretherketone (PEEK, ASTM F-2026) Titanium marker (ASTM F-67)		Polyetherketone Ether Ketone Ketone (PEKEKK) with Polyacrylonitrile (PAN) carbon fibers with Tantalum markers	

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

Characteristic	Standard / Test/ FDA Guidance
Static Compression	ASTM F 2077-03
Dynamic Compression	ASTM F 2077-03
Subsidence	ASTM F2267-04

Performance Data Summary

Mechanical testing of the Orthofix Inc. FORZA™ Spacer System was conducted in accordance to ASTM F2077-03 standard for Static & Dynamic Compression testing and ASTM F2267-04 standards for Subsidence testing. Test results demonstrated that

the FORZA Space system is substantially equivalent to predicate devices that have the same intended use, similar indications, technological characteristics and principles of operation.

Substantial Equivalence

The FORZA™ Spacer System share the same intended use, similar indications, technological characteristics and principles of operation with PILLAR Spacer System (K081177) and the DePuy Acromed, Inc. Lumbar I/F Cage® with VSP Spine System (P960025). FORZA system has similar mechanical properties to DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP Spine System (P960025) and Pioneer Rotate Option implant (K073177) predicate device as stated above.

The difference between FORZA Space System implants and its predicate devices consist in technological differences i.e. the FORZA implants are distributed sterile and have minor dimensional differences. FORZA dimensional and sterility differences proposed in this submission are addressed with sterilization and mechanical verification testing. Based on test results, these changes do not present any new / additional issues of safety or effectiveness, therefore, the FORZA™ Spacer System is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Orthofix, Inc.
% Ms. Darla Chew
Director of Regulatory Affairs
3451 Plano Parkway
Lewisville, Texas 75056

MAR 23 2011

Re: K103111
Trade/Device Name: FORZA™ Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 18, 2011
Received: March 21, 2011

Dear Ms. Chew:

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.

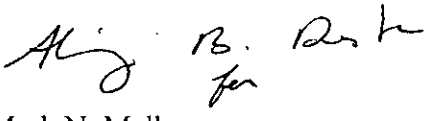
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103111

Device Name: FORZA™ Spacer System
(Intervertebral body fusion device)

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103111