510(k) SUMMARY

NOV 29 2012

CONSTRUX Mini® PEEK Ti Spacer System

Submitter Information

Name: Orthofix Inc.
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Lewisville, TX 75056

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Contact Person: Natalia Volosen
Senior Regulatory Affairs Specialist

Date Prepared: November 28, 2012

Name of Device

Trade Name / Proprietary Name: CONSTRUX Mini® PEEK Ti Spacer System

Common Name: Intervertebral body fusion device

Product Code: ODP – cervical intervertebral fusion device with bone graft

Regulatory Classification: Class II – 21CFR 888.3080 – Intervertebral body fusion device

Review Panel: Orthopedic Device Panel

Predicate Devices: K101812 – CONSTRUX Mini PEEK Spacer System, SE 9-27-10
K100889 – Titan Spine Endoskeleton TC, SE 7-29-10

Reason for 510(k) Submission: New product offering

Device Description

The CONSTRUX Mini PEEK Ti Spacer System is comprised of a variety of implants that has a PEEK core with integrated porous Titanium end plates. The CONSTRUX Mini PEEK Ti 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 vertebrate onto another.

The CONSTRUX Mini PEEK Ti Spacer System is not intended to be used as a stand-alone device. The CONSTRUX Mini PEEK Ti Spacer System must be used with supplemental fixation. The CONSTRUX Mini PEEK Ti implants are provided sterile.

Intended Use / Indications for Use

The CONSTRUX Mini PEEK Ti Spacer System is indicated for spinal fusion procedures at one level in 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 PEEK Ti Spacer System is intended for use with autograft and supplemental fixation system (i.e. anterior cervical plate such as the Orthofix ACP or Hallmark® System).

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PEEK Ti Spacer System in the cervical spine.

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

Characteristic	Subject Device	Predicates	
Device Name	CONSTRUX Mini PEEK Ti Spacer System	CONSTRUX Mini PEEK Spacer System (K101812)	Titan Spine Endoskeleton TC (K100889)
Method of Fixation	IBD spacer used with autograft and supplemental fixation	IBD spacer used with autograft and supplemental fixation	IBD spacer used with autograft and supplemental fixation
Implantation	Anterior approach	Anterior approach	Anterior approach
Design	Hollow cage	Hollow cage	Hollow cage
Profile	Parallel and lordotic	Parallel and lordotic	Parallel and lordotic
Material	Polyetheretherketone and Titanium alloy (Ti-6Al-4V)	Polyetheretherketone) and commercially pure Titanium	Titanium alloy (Ti-6Al-4V)

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

Characteristic	Standard / Test/ FDA Guidance
Static and Dynamic Torsion Test	ASTM F2077-11
Static and Dynamic Axial Compression Test	ASTM F2077-11
Static and Dynamic Compression Shear Test	ASTM F2077-11
Subsidence Test	ASTM F2267-04

Performance Data Summary

Mechanical testing for the CONSTRUX Mini PEEK Ti Spacer System was conducted in accordance to ASTM F2077-11 standard for Test Method for Intervertebral Body Fusion Devices and in accordance to ASTM F2267-04 standard for Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device. Test results demonstrated that the new, proposed device is substantially equivalent to predicate device that have the same intended use, similar indications, technological characteristics and principles of operation.

Basis of Substantial Equivalence
The new CONSTRUX Mini PEEK Ti Spacer System is substantially equivalent in design, configuration, function, indications for use and materials to the CONSTRUX Mini PEEK Spacer System and Titan Spine Endoskeleton TC device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Orthofix Incorporated
% Ms. Natalia Volosen
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Letter dated: November 29, 2012

Re: K121649
Trade/Device Name: CONSTRUX Mini PEEK Ti Spacer System
Regulation Number: 21 CFR 888.3080
Regulatory Class: II
Product Code: ODP
Dated: October 23, 2012
Received: October 24, 2012

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.

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

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): K121649

Device Name: CONSTRUX Mini® PEEK Ti Spacer System

Indications for Use:

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Prescription Use: X (Part 21 CFR 801 Subpart D) And / Or Over-The-Counter_____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Caroline Rhim -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K121649