DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 8, 2015

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

Re: K142152
Trade/Device Name: CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System, and Cervical Stand Alone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, OVE, MQP
Dated: December 10, 2014
Received: December 11, 2014

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 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,

Lori A. Wiggins -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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142152

Device Name
CONSTRUX Mini PEEK Spacer System
CONSTRUX Mini PEEK Ti Spacer System
Cervical Stand Alone System

Indications for Use *(Describe)*

CONSTRUX Mini PEEK Spacer System

When used as a cervical intervertebral body fusion device, the CONSTRUX Mini PEEK 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 Spacer System is intended for use with autograft and /or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, e.g.: the Ascent™ or Ascent LE™ POCT 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 Spacer System in the cervical spine.

When used as a Partial Vertebral Body Replacement (VBR) System, the CONSTRUX Mini PEEK Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The CONSTRUX Mini PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The CONSTRUX Mini PEEK Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The Partial VBR device is intended to be used with autograft or allograft.
The CONSTRUX Mini PEEK Spacer System is intended for use with internal fixation. The supplemental internal fixation system that may be used with the CONSTRUX Mini PEEK Spacer System is the Orthofix Spinal Fixation System (SFS) or the Firebird Spinal Fixation System.

CONSTRUX Mini PEEK Ti Spacer System

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 /or allograft comprised of cancellous and/or corticocancellous bone graft 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.

Cervical Stand Alone System

The Cervical Stand Alone 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 Cervical Stand Alone System is used with autograft and /or allograft comprised of cancellous and/or corticocancellous bone graft and the two titanium alloy screws which accompany the implant.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Cervical Stand Alone System in the cervical spine.

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

PEEK Cervical Interbody Device

510(k) Owner Information

Name: Orthofix Inc.
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Contact Person: Natalia Volosen
Senior Regulatory Affairs Specialist

Date Prepared: December 10, 2014

Name of Device

Trade Name / Proprietary Name: CONSTRUX Mini PEEK Spacer System
CONSTRUX Mini PEEK Ti Spacer System
Cervical Stand Alone System

Common Name: Intervertebral body fusion device
Spinal intervertebral body fixation orthosis

Product Code: ODP, MQP, OVE

Regulatory Classification: Class II per 21 CFR § 888.3080
Class II per 21 CFR § 888.3060

Review Panel: Orthopedic Device Panel

Predicate Devices: K130177 – Medtronic ANATOMIC PEEK™ CERVICAL FUSION SYSTEM, SE 9/23/2013 (primary predicate)
K133653 – Medtronic ANATOMIC PEEK PTC Cervical Fusion System, SE 4/28/2014 (additional predicate)
K132999 – Cervical Stand Alone System, SE 04/14/2014 (additional predicate)
K101812 – CONSTRUX Mini PEEK Spacer System, SE 09/27/2010 (additional predicate)
K121649 – CONSTRUX Mini PEEK Ti Spacer System, SE 11/29/2012 (additional predicate)
No reference devices were used in this submission

Reason for 510(k) Submission: Expanded Indications for Use

Device Description

CONSTRUX Mini PEEK Spacer System:
The CONSTRUX Mini PEEK Spacer System is comprised of a variety of implants manufactured from PEEK and with titanium markers. The implants are available in two footprint sizes, a small and a large. The implants are available in various heights, in one-millimeter increments. The

superior and inferior surfaces of the implant have a pattern of ridges to provide increased stability and help prevent anterior/posterior movement of the device.

CONSTRUX Mini PEEK Ti Spacer System:
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 superior and inferior Titanium plate surfaces of the implant provide increased stability for the implant. The implants are available in three footprint sizes and various heights. 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.

Cervical Stand Alone System
The Cervical Stand Alone Spacer system is designed to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The Cervical Stand Alone spacer is manufactured from PEEK and Titanium with Titanium bone screws that allow intradiscal fixation to the vertebral body. The superior and inferior surfaces of the implant have a pattern of ridges that provide increased stability and help prevent migration of the device.

Intended Use / Indications for Use
CONSTRUX Mini PEEK Spacer System
When used as a cervical intervertebral body fusion device, the CONSTRUX Mini PEEK 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 Spacer System is intended for use with autograft and /or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, e.g.: the Ascent™ or Ascent LE™ POCT 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 Spacer System in the cervical spine.

When used as a Partial Vertebral Body Replacement (VBR) System, the CONSTRUX Mini PEEK Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The CONSTRUX Mini PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The CONSTRUX Mini PEEK Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The Partial VBR device is intended to be used with autograft or allograft.

The CONSTRUX Mini PEEK Spacer System is intended for use with internal fixation. The supplemental internal fixation system that may be used with the CONSTRUX Mini PEEK Spacer System is the Orthofix Spinal Fixation System (SFS) or the Firebird Spinal Fixation System.

CONSTRUX Mini PEEK Ti Spacer System
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 /or allograft comprised of cancellous and/or corticocancellous bone graft 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.

Cervical Stand Alone System
The Cervical Stand Alone 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 Cervical Stand Alone System is used with autograft and /or allograft comprised of cancellous and/or corticocancellous bone graft and the two titanium alloy screws which accompany the implant.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Cervical Stand Alone System in the cervical spine.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices
The technological characteristics of the CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System and Cervical Stand Alone Spacer System are similar to the predicate devices in terms of indication for use, intended use, design and materials.

There may be differences in implant foot print and size which will not introduce additional risk to the patients as these devices are currently being cleared for distribution. The addition of the allograft comprised of cancellous and/or corticocancellous bone graft to the CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System and Cervical Stand Alone Spacer System indication do not raise new types of safety and effectiveness questions (risks) not seen before. The same risks occur in the subject CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System and Cervical Stand Alone Spacer System as in the predicate devices.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence
There have been no design changes made to CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System, and Cervical Stand Alone System implants. The purpose of this 510(k) submission is to obtain clearance to use allograft bone comprised of cancellous and/or corticocancellous bone graft as a substitute to autograft bone. No mechanical testing was performed to help determine substantial equivalence.

PERFORMANCE DATA – Summary of Clinical Test Conducted for Determination of Substantial Equivalence
Published retrospective clinical data for the cervical interbody fusion devices similar to the CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System, and Cervical Stand Alone System implants was provided in support of this application. The published clinical outcomes demonstrated that the use of allograft (cancellous and/or

corticocancellous bone graft) in anterior cervical interbody fusion procedures to treat patients diagnosed with cervical disc disease as defined above poses no new risks to patients. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

Basis of Substantial Equivalence
The CONSTRUX Mini PEEK Spacer system, CONSTRUX Mini PEEK Ti Spacer system and Cervical Stand Alone system have the same intended use, similar indications for use, the similar technological characteristics and design, same materials and the same principles of operation as the to the Medtronic ANATOMIC PEEK™ CERVICAL FUSION SYSTEM (K130177) and Medtronic ANATOMIC PEEK PTC Cervical Fusion System (K133653).

The minor differences between CONSTRUX Mini PEEK Spacer system, CONSTRUX Mini PEEK Ti Spacer system and Cervical Stand Alone system implant design and the Medtronic ANATOMIC PEEK™ CERVICAL FUSION SYSTEM (K130177) and Medtronic ANATOMIC PEEK PTC Cervical Fusion System (K133653) predicates does not introduce any additional patient risk.

There have been no design changes made to CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System, and Cervical Stand Alone System implants since their last 510(k) clearance. The purpose of this 510(k) submission is to obtain clearance to use allograft bone comprised of cancellous and/or corticocancellous bone graft as a substitute / addition to autograft bone.