



October 29, 2020

Orthofix Inc.
Ms. Natalia Volosen
Regulatory Affairs Principal
3451 Plano Parkway
Lewisville, Texas 75056

Re: K202949

Trade/Device Name: CONSTRUX Mini PEEK Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: September 29, 2020
Received: September 30, 2020

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 L. 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

Indications for Use

510(k) Number (if known)
K202949

Device Name
CONSTRUX Mini PEEK Spacer System

Indications for Use (Describe)

When used as a cervical intervertebral body fusion device, the CONSTRUX Mini PEEK Spacer System is indicated for spinal fusion procedures at one or two contiguous levels within 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 system; the hyperlordotic implants ($\geq 10^\circ$) are required to be used with an anterior cervical plate.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PTC 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. Lordotic implants greater than a 5° profile are not to be used for partial vertebral body replacement.

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 and supplemental fixation 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.

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510(k) Summary

Device Trade Name: CONSTRUX Mini PEEK Spacer System

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

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

Date Prepared: September 29, 2020

Registration Number: 2183449

Product Code: ODP, MQP

Classifications: Class II – 21 CFR §888.3080, Intervertebral body fusion device
Class II – 21 CFR §888.3060, Spinal vertebral body replacement device

Primary Predicate: K150619 – CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System, SE 9/11/2015

Additional Predicate: K193359 – SureMAX™ Family of Cervical Spacers, SE 1/3/2020

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

Device Description:

The CONSTRUX Mini PTC Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone), as described by ASTM F2026, with titanium markers as described by ASTM F67. The implants are available in multiple sizes to accommodate various patient anatomies. The superior and inferior surfaces of the implant have a pattern of ripples to provide increased stability and help prevent anterior/posterior movement of the device.

The CONSTRUX Mini PEEK Spacer System is not intended to be used as a standalone device. The CONSTRUX Mini PEEK Spacer System must be used with a supplemental fixation system.

Indications for Use and Intended Use:

When used as a cervical intervertebral body fusion device, the CONSTRUX Mini PEEK Spacer System is indicated for spinal fusion procedures at one or two contiguous levels within 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 system; the hyperlordotic implants ($\geq 10^\circ$) are required to be used with an anterior cervical plate.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the CONSTRUX Mini PTC 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. Lordotic implants greater than a 5° profile are not to be used for partial vertebral body replacement.

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 and supplemental fixation system.

Performance Testing Summary:

The modified CONSTRUX Mini PEEK spacer was evaluated via mechanical testing per ASTM F2077 (including static and dynamic axial compression, static and dynamic compression shear and static and dynamic torsion) and ASTM F2267 (subsidence). The results demonstrated the performance of the modified cervical spacer is substantially equivalent to the predicate device.

Substantial Equivalence:

The subject device is substantially equivalent to the CONSTRUX Mini PEEK Spacer System (K150619) primary predicate and SureMAX™ Family of Cervical Spacers (K193359) additional predicate with respect to indications, design, materials, function, and performance.

Conclusion:

CONSTRUX Mini PEEK Spacer System have the same intended use, indications for use, technological characteristics, materials, the same principles of operation and same design as the predicate device CONSTRUX Mini PEEK Spacer System (K150619) and SureMAX™ Family of Cervical Spacers (K193359).