August 31, 2021

Orthofix Inc.
Jacki Koch
Principle Regulatory Affairs
3451 Plano Parkway
Lewisville, Texas 75056

Re: K211704
Trade/Device Name: CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System, CONSTRUX Mini PTC Spacer System, CONSTRUX Mini Ti Spacer System, FORZA PEEK Spacer System, FORZA PTC Spacer System, FORZA Ti Spacer System, FORZA XP Expandable Spacer System, Lonestar Cervical Standalone System, PILLAR PEEK Spacer System, PILLAR SA PEEK Spacer System, PILLAR SA PTC Spacer System, SKYHAWK Lateral Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MQP, MAX, OVD, OVE
Dated: June 2, 2021
Received: June 3, 2021

Dear Jacki Koch:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211704

Device Name

CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System

Indications for Use *(Describe)*

When Used as a Cervical Intervertebral Body Fusion System:
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 (≥10°) 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 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. 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)

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Indications for Use

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510(k) Number *(if known)*
K211704

Device Name
CONSTRUX Mini PTC Spacer System

Indications for Use *(Describe)*
The CONSTRUX Mini PTC 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 PTC 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 (≥10°) 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.

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)

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Device Name
CONSTRUX Mini Ti Spacer System

Indications for Use *(Describe)*

The CONSTRUX Mini Ti 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 Ti 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 (≥10°) 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 Ti Spacer 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)

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510(k) Number *(if known)*
K211704

Device Name
FORZA PEEK Spacer System

Indications for Use *(Describe)*
The FORZA Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The FORZA Spacer System is intended to be used with supplemental fixation systems. As an example, the supplemental fixation that may be used is the Orthofix Firebird Spinal Fixation System.

The FORZA Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

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)

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Device Name
FORZA PTC Spacer System

Indications for Use *(Describe)*

The FORZA PTC 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 levels.

The FORZA PTC 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 Firebird Spinal Fixation System.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the FORZA PTC 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)

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510(k) Number *(if known)*
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Device Name
FORZA Ti Spacer System

Indications for Use *(Describe)*
The FORZA Ti 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 levels.

The FORZA Ti 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 the FORZA Ti 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)

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510(k) Number *(if known)*
K211704

Device Name
FORZA XP Expandable Spacer System

Indications for Use *(Describe)*
The 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).

The 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 system.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the 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)

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510(k) Number *(if known)*
K211704

Device Name
Lonestar Cervical Standalone System

Indications for Use *(Describe)*
The LONESTAR 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 LONESTAR 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 weeks of non-operative treatment prior to being treated with the LONESTAR 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)

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510(k) Number *(if known)*
K211704

Device Name
PILLAR PEEK Spacer System

Indications for Use *(Describe)*
The PILLAR PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The PILLAR PEEK Spacer System is intended to be used with supplemental fixation. As an example, the supplemental fixation that may be used is the Orthofix Spinal Fixation System (SFS).

The PILLAR PL PEEK Spacer is used singly or in pairs and is implanted using a posterior approach.

The PILLAR TL PEEK Spacer is used singly or in pairs and is implanted using a transforaminal approach.

The PILLAR AL PEEK Spacer is used singly and is implanted using an anterior approach.

The PILLAR XL PEEK Spacer is used singly and is implanted using a lateral approach.

The PILLAR PEEK Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

When used as a Partial Vertebral Body Replacement (VBR) Device:
The PILLAR 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 PILLAR Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

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

The PILLAR PEEK Spacer System is intended for use with supplemental fixation. As an example, the supplemental fixation that may be used is the Orthofix Spinal Fixation System (SFS).

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)

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K211704

Device Name
PILLAR SA PEEK Spacer System

Indications for Use *(Describe)*

When used as an Intervertebral Body Fusion Device:
The PILLAR SA PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The PILLAR SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental fixation must be used to augment stability. As an example, the supplemental fixation system that may be used is the Orthofix Firebird Spinal Fixation System.

The PILLAR SA PEEK Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

When used as a Partial Vertebral Body Replacement (VBR) Device:
The PILLAR SA 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 PILLAR SA PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR SA 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 PILLAR SA PEEK Spacer System is intended to be used with autograft or allograft.

The PILLAR SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental fixation must be used to augment stability. As an example, the supplemental fixation that may be used is the Orthofix Firebird Spinal Fixation System.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*

K211704

Device Name
PILLAR SA PTC Spacer System

Indications for Use *(Describe)*

The PILLAR SA PTC 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 PILLAR SA PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The PILLAR SA PTC Spacer System is intended for use with four of the titanium alloy screws provided with the system. If the physician chooses to use fewer than four of the provided screws then supplemental fixation must be used to augment stability. As an example, a supplemental fixation system that may be used is the Orthofix Firebird® Spinal Fixation System.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the PILLAR SA PTC 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211704

Device Name
SKYHAWK Lateral Interbody Fusion System

Indications for Use *(Describe)*
When used as an intervertebral body fusion device, the SKYHAWK Lateral Interbody Fusion System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The SKYHAWK Lateral Interbody Fusion System is intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.

The SKYHAWK Lateral Interbody Fusion System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

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

CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System
CONSTRUX Mini PTC Spacer System
CONSTRUX Mini Ti Spacer System
FORZA PEEK Spacer System
FORZA PTC Spacer System
FORZA Ti Spacer System
FORZA XP Expandable Spacer System
Lonestar Cervical Standalone System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
PILLAR SA PTC Spacer System
SKYHAWK Lateral Interbody Fusion System

510(k) Owner Information

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Date Prepared: August 30, 2021

Name of Device

Trade Name / Proprietary Name:

CONSTRUX Mini PEEK Spacer System/
CONSTRUX Mini PEEK VBR System (K202949)
CONSTRUX Mini PTC Spacer System (K202666)
CONSTRUX Mini Ti Spacer System (K203342)
FORZA PEEK Spacer System (K162446)
FORZA PTC Spacer System (K200052)
FORZA Ti Spacer System (K203576)
FORZA XP Expandable Spacer System (K172696)
Lonestar Cervical Standalone System (K161280)
PILLAR PEEK Spacer System (K162446)
PILLAR SA PEEK Spacer System (K162446)
PILLAR SA PTC Spacer System (K200052)
SKYHAWK Lateral Interbody Fusion System (K162446)

Product Code(s):

System Name	Product Codes
CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK Vertebral Body Replacement System	ODP, MQP
CONSTRUX Mini PTC Spacer System	ODP
CONSTRUX Mini Ti Spacer System	ODP

FORZA PEEK Spacer System	MAX, MQP
FORZA PTC Spacer System	OVD, MAX, ODP
FORZA Ti Spacer System	MAX
FORZA XP Expandable Spacer System	MAX
Lonestar Cervical Standalone System	OVE
PILLAR PEEK Spacer System	MAX, MQP
PILLAR SA PEEK Spacer System	MAX, MQP
PILLAR SA PTC Spacer System	OVD, MAX, ODP
SKYHAWK Lateral Interbody Fusion System	MAX, MQP

Classification Name(s)

System Name	Classification Name
CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK Vertebral Body Replacement System	Intervertebral Body Fusion Device
CONSTRUX Mini PTC Spacer System	Intervertebral Body Fusion Device
CONSTRUX Mini Ti Spacer System	Intervertebral Body Fusion Device
FORZA PEEK Spacer System	Intervertebral Body Fusion Device
FORZA PTC Spacer System	Intervertebral Body Fusion Device
FORZA Ti Spacer System	Intervertebral Body Fusion Device
FORZA XP Expandable Spacer System	Intervertebral Body Fusion Device
Lonestar Cervical Standalone System	Intervertebral Body Fusion Device
PILLAR PEEK Spacer System	Intervertebral Body Fusion Device
PILLAR SA PEEK Spacer System	Intervertebral Body Fusion Device
PILLAR SA PTC Spacer System	Intervertebral Body Fusion Device
SKYHAWK Lateral Interbody Fusion System	Intervertebral Body Fusion Device

Device Classification

System Name	Product Codes
CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK Vertebral Body Replacement System	Class II per 21 CFR § 888.3080
CONSTRUX Mini PTC Spacer System	Class II per 21 CFR § 888.3080
CONSTRUX Mini Ti Spacer System	Class II per 21 CFR § 888.3080
FORZA PEEK Spacer System	Class II per 21 CFR § 888.3080
FORZA PTC Spacer System	Class II per 21 CFR § 888.3080
FORZA Ti Spacer System	Class II per 21 CFR § 888.3080
FORZA XP Expandable Spacer System	Class II per 21 CFR § 888.3080
Lonestar Cervical Standalone System	Class II per 21 CFR § 888.3080
PILLAR PEEK Spacer System	Class II per 21 CFR § 888.3080
PILLAR SA PEEK Spacer System	Class II per 21 CFR § 888.3080
PILLAR SA PTC Spacer System	Class II per 21 CFR § 888.3080
SKYHAWK Lateral Interbody Fusion System	Class II per 21 CFR § 888.3080

Review Panel: Orthopedic Device Panel

Predicate Device: FORZA Ti Spacer System (K203576)

Additional Predicate Devices: CONSTRUX Mini PEEK Spacer System/
CONSTRUX Mini PEEK VBR System (K202949)
CONSTRUX Mini PTC Spacer System (K202666)
CONSTRUX Mini Ti Spacer System (K203342)
FORZA PEEK Spacer System (K162446)
FORZA PTC Spacer System (K200052)
FORZA XP Expandable Spacer System (K172696)
Lonestar Cervical Standalone System (K161280)
PILLAR PEEK Spacer System (K162446)

PILLAR SA PEEK Spacer System (K162446)
PILLAR SA PTC Spacer System (K200052)
SKYHAWK Lateral Interbody Fusion System (K162446)

Reason for 510(k) Submission:
Orthofix is submitting this Special 510(k) premarket notification for the addition of MR Conditional labeling to the subject medical devices.

The subject addition of MR Conditional labeling does not change the design, intended use, materials, performance specifications or the indications for use as previously cleared.

Device Description
CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System – The CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone), as described by ASTM F2026, with titanium markets 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 VBR System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine.

The CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System is not intended to be used as a stand-alone device and must be used with supplemental fixation. The implants are used singly and are implanted using an anterior approach.

The CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System implants are provided either in a sterile packaging configuration or non-sterile and requires sterilization prior to use.

CONSTRUX Mini PTC Spacer System - The CONSTRUX Mini PTC Spacer System is comprised of a variety of implants that have a PEEK core with integrated porous titanium end plates. CONSTRUX Mini PTC spacers are implanted in the cervical intervertebral disc space and are intended to facilitate vertebral fusion by stabilizing adjacent vertebrae, maintaining disc height and preventing the collapse of one vertebra onto another.

The CONSTRUX Mini PTC Spacer System is not intended to be used as a stand-alone device and must be used with supplemental fixation. The implants are used singly and are implanted using an anterior approach.

The CONSTRUX Mini PTC implants are provided sterile.

CONSTRUX Mini PTC implants are design to be used with CONSTRUX Mini PEEK Spacer System instrumentation. The CONSTRUX Mini PTC implants are not compatible with components or metal from any other manufacturer's system.

CONSTRUX Mini Ti Spacer System - The CONSTRUX Mini Ti Spacer System is comprised of a variety of 3D printed implants that have porous titanium end plates and a functional gradient porous structure. CONSTRUX Mini Ti spacers are implanted in the cervical intervertebral disc space and are intended to facilitate vertebral fusion by stabilizing adjacent vertebrae, maintaining disc height and preventing the collapse of one vertebra onto another.

The CONSTRUX Mini Ti Spacer System is not intended to be used as a stand-alone device and must be used with supplemental fixation. The implants are used singly and are implanted using an anterior approach.

The CONSTRUX Mini Ti implants are provided sterile.

CONSTRUX Mini Ti implants are design to be used with CONSTRUX Mini Spacer System instrumentation. The CONSTRUX Mini Ti implants are not compatible with components or metal from any other manufacturer's system.

FORZA PEEK Spacer System - The FORZA Spacer System consists of implants, trials and instruments. The system is comprised of a variety of implants fabricated and manufactured from polyetheretherketone (PEEK) as described by ASTM F2026 with tantalum markers as described by ASTM F560. PEEK is utilized due to its radiolucent properties, which aid 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 intraoperatively and postoperatively.

FORZA Spacer System implants are offered in two geometric shapes – straight and curved, and offered in parallel and lordotic profiles to restore the natural curvature of the spine. The implants can be used in single placement or in pairs. 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 and are implanted using a posterior approach.

The FORZA Spacer System is not intended to be used as a stand-alone device. The FORZA Spacer System must be used with a supplemental fixation system. The implants are provided sterile but the instruments are provided non-sterile and require sterilization prior to use.

FORZA PTC Spacer System - The FORZA PTC Spacer System is comprised of a variety of implants that have a PEEK (OPTIMA LT1) core with integrated porous titanium (Ti-6Al-4V) end plates as well as a tantalum marker that acts as a visual aid for the surgeon in determining the location of the implant both intraoperatively and postoperatively.

FORZA PTC Spacer System implants are offered in two geometric shapes – straight and curved, and offered in parallel and lordotic profiles to restore the natural curvature of the spine. The implants can be used in single placement or in pairs. Both the curved and straight implants feature a bulleted nose for ease of insertion and a roughened surface on both the inferior and superior faces of the implant to provide increased stability and help prevent anterior/posterior movement of the device.

The FORZA PTC Spacer System is intended for intervertebral body fusion to aid in the surgical correction of the spine and are implanted using a posterior approach.

The FORZA PTC Spacer System is not intended to be used as a standalone device. The FORZA PTC Spacer System must be used with a supplemental fixation system.

The FORZA PTC Spacer System implants are provided sterile.

FORZA PTC implants are designed for use with FORZA PEEK Spacer System instrumentation. The FORZA PTC spacers are not compatible with components or metal from any other manufacturer's system.

FORZA Ti Spacer System - The FORZA Ti Spacer System is comprised of a variety of 3D printed implants that have porous titanium end plates and a functional gradient porous structure.

FORZA Ti Spacer System implants are offered in two geometric shapes – straight and curved, and offered in parallel and lordotic profiles to restore the natural curvature of the spine. The implants can be used in single placement or in pairs. Both the curved and straight implants feature a bulleted nose for ease of insertion and a roughened surface on both the inferior and

superior faces of the implant to provide increased stability and help prevent anterior/posterior movement of the device.

The FORZA Ti Spacer System is intended for intervertebral body fusion to aid in the surgical correction of the spine and are implanted using a posterior approach.

The FORZA Ti Spacer System is not intended to be used as a standalone device. The FORZA Ti Spacer System must be used with a supplemental fixation system.

The FORZA Ti Spacer System implants are provided sterile.

FORZA Ti implants are designed for use with FORZA PEEK and FORZA PTC Spacer System instrumentation. The FORZA Ti spacers are not compatible with components or metal from any other manufacturer's system.

FORZA XP Expandable Spacer System - The FORZA XP Expandable Spacer System is comprised of an assortment of non-sterile, single use, titanium alloy (Ti-6Al-4V ELI per ASTM F136) and Polyetheretherketone (PEEK) Polymer (PEEK OPTIMA® LT1 per ASTM F2026) spacers with height expansion capability. The expandable interbody spacer is inserted into the lumbar disc space and expanded to fit the patient anatomy.

The implants are offered in parallel, 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 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 XP Expandable Spacer System is not intended to be used as a stand-alone device. The system must be used with a supplemental fixation system, is provided non-sterile and requires sterilization prior to use.

Lonestar Cervical Standalone System - The LONESTAR Cervical Stand Alone System is a stand-alone spacer system designed to provide biomechanical strength to a traditional or minimally invasive ACDF procedure with less disruption of patient anatomy and preservation of the anatomical profile. The system helps to preserve the natural sagittal anatomic profile of the cervical spine while providing anterior column support and stability.

The LONESTAR implant consists of a hybrid PEEK and titanium spacer along with titanium bone screws and a titanium cover plate. The spacers are designed with a zero degree anterior profile and are implanted using an anterior approach.

The LONESTAR Cervical Stand Alone implants and instruments are provided non-sterile and will require thorough cleaning and sterilization prior to each use. The implants are not compatible with components or metal from any other manufacturer's system.

PILLAR PEEK Spacer System - The PILLAR PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone) as described by ASTM F2026 with tantalum markers as described by ASTM F560. The implants are available in a variety of sizes and are offered in parallel and lordotic profiles in order to restore the natural curvature of the spine. The implants are available in various heights in either one or two millimeter increments. 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 PILLAR PEEK Spacer System is intended for intervertebral body fusion or partial vertebral body replacement to aid in the surgical correction and stabilization of the spine.

The PILLAR PEEK Spacer System is not intended to be used as a stand-alone device and must be used with supplemental fixation. The system is provided non-sterile and requires sterilization prior to use.

PILLAR SA PEEK Spacer System - The PILLAR SA PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone) as described by ASTM F2026 with tantalum markers as described by ASTM F560. The implants are available in multiple footprints, a variety of heights, and two angles of lordosis: 7° and 12°. The implants incorporate integrated anterior screw holes to allow for medial placement of screws, as well as a titanium plate for securing the screws once in place. The superior and inferior surfaces of the implant have a pattern of ripples that provide increased stability and help prevent movement of the device.

The PILLAR SA PEEK Spacer System is provided non-sterile.

PILLAR SA PTC Spacer System - The PILLAR SA PTC Spacer System is comprised of a variety of implants that have a PEEK core with integrated porous titanium end plates. The implants incorporate integrated anterior screw holes to allow for medial placement of bone screws as well as a titanium plate for securing the bone screws once in place. The implants are designed with a roughened surface on the inferior and superior faces of the implant to provide increased stability and help prevent anterior/posterior movement of the device.

The PILLAR SA PTC Spacer System is intended for intervertebral body fusion to aid in the surgical correction of the spine and is implanted using an anterior approach.

The PILLAR SA PTC spacers are provided sterile. The cover plate, screws and instruments are provided non-sterile and require sterilization prior to use.

The PILLAR SA PTC implants are designed to be used with PILLAR SA PEEK Spacer System instrumentation. The implants are not compatible with components from any other manufacturer's system.

SKYHAWK Lateral Interbody Fusion System - The SKYHAWK Lateral Interbody Fusion System consists of implants, trials, and instruments and is comprised of a variety of implants fabricated and manufactured from polyetheretherketone (PEEK) as described by ASTM F2026 with tantalum markers as described by ASTM F560. PEEK is utilized due to its radiolucent property, 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 intraoperatively and postoperatively.

The SKYHAWK Lateral Interbody Fusion System implants are offered in parallel and lordotic profiles to restore the natural curvature of the spine; the device may be implanted using a lateral or anterolateral approach.

The SKYHAWK Lateral Interbody Fusion System implants, trials and instruments are provided non-sterile. They require sterilization prior to use.

Intended Use / Indications for Use

CONSTRUX Mini PEEK Spacer System/CONSTRUX Mini PEEK VBR System

When Used as a Cervical Intervertebral Body Fusion System:

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 (≥10°) 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 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. 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.

CONSTRUX Mini PTC Spacer System
The CONSTRUX Mini PTC 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 PTC 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 (≥10°) 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.

CONSTRUX Mini Ti Spacer System
The CONSTRUX Mini Ti 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 Ti 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 (≥10°) 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 Ti Spacer System in the cervical spine.

FORZA PEEK Spacer System
The FORZA Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The FORZA Spacer System is intended to be used with supplemental fixation systems. As an example, the supplemental fixation that may be used is the Orthofix Firebird Spinal Fixation System.

The FORZA Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

FORZA PTC Spacer System

The FORZA PTC 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 levels.

The FORZA PTC 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 Firebird Spinal Fixation System.

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

FORZA Ti Spacer System

The FORZA Ti 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 levels.

The FORZA Ti 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 the FORZA Ti Spacer System.

FORZA XP Expandable Spacer System

The 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).

The 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 system.

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

Lonestar Cervical Standalone System

The LONESTAR 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 LONESTAR 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 weeks of non-operative treatment prior to being treated with the LONESTAR Cervical Stand Alone System in the cervical spine.

PILLAR PEEK Spacer System

The PILLAR PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The PILLAR PEEK Spacer System is intended to be used with supplemental fixation. As an example, the supplemental fixation that may be used is the Orthofix Spinal Fixation System (SFS).

The PILLAR PL PEEK Spacer is used singly or in pairs and is implanted using a posterior approach.

The PILLAR TL PEEK Spacer is used singly or in pairs and is implanted using a transforaminal approach.

The PILLAR AL PEEK Spacer is used singly and is implanted using an anterior approach.

The PILLAR XL PEEK Spacer is used singly and is implanted using a lateral approach.

The PILLAR PEEK Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

When used as a Partial Vertebral Body Replacement (VBR) Device:
The PILLAR 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 PILLAR Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

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

The PILLAR PEEK Spacer System is intended for use with supplemental fixation. As an example, the supplemental fixation that may be used is the Orthofix Spinal Fixation System (SFS).

PILLAR SA PEEK Spacer System

When used as an Intervertebral Body Fusion Device:
The PILLAR SA PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The PILLAR SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental fixation must be used to augment stability. As an example, the supplemental fixation system that may be used is the Orthofix Firebird Spinal Fixation System.

The PILLAR SA PEEK Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

When used as a Partial Vertebral Body Replacement (VBR) Device:
The PILLAR SA 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 PILLAR SA PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR SA 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 PILLAR SA PEEK Spacer System is intended to be used with autograft or allograft.

The PILLAR SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental fixation must be used to augment stability. As an example, the supplemental fixation that may be used is the Orthofix Firebird Spinal Fixation System.

PILLAR SA PTC Spacer System
The PILLAR SA PTC 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 PILLAR SA PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The PILLAR SA PTC Spacer System is intended for use with four of the titanium alloy screws provided with the system. If the physician chooses to use fewer than four of the provided screws then supplemental fixation must be used to augment stability. As an example, a supplemental fixation system that may be used is the Orthofix Firebird® Spinal Fixation System.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the PILLAR SA PTC Spacer System.

SKYHAWK Lateral Interbody Fusion System
When used as an intervertebral body fusion device, the SKYHAWK Lateral Interbody Fusion System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The SKYHAWK Lateral Interbody Fusion System is intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.

The SKYHAWK Lateral Interbody Fusion System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

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

The Technological Characteristics, design, dimensions, intended use, materials and performance characteristics of the subject devices are unchanged from their previous clearance. The purpose of this 510(k) submission is for the addition of MR Conditional to the device labeling.

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

In accordance to the FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" the following testing was conducted:

- ASTM F2052-15 – Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment
- ASTM F2213-17 – Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment
- ASTM F2119-07 – Standard test method for evaluation of MR image artifacts from passive implants
- ASTM F2182-19E2 - Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging

Basis of Substantial Equivalence

As stated throughout this 510(k) notification, there are no modifications to the design, intended use, or indications for use. The purpose of this 510(k) notification is for the addition of MR Conditional labeling for the subject devices.

The subject devices are temporary, multiple component systems comprised of a variety of single use components. There have been no changes to the design, to the material, intended use or indications for use.

Therefore, the subject devices are identical to themselves as previously cleared.

In accordance with FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment," the following testing was conducted to determine that the subject devices met requirements necessary for MRI Conditional labeling:

- ASTM F2052-15 **-** "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment"
- ASTM F2213-17 **-** "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment"
- ASTM F2119-07 - "Standard test method for evaluation of MR image artifacts from passive implants"
- ASTM F2182-19E2 **-** "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging"
- ASTM F2503 **-** "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment"