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

December 22, 2016

ORTHOFIX Inc.
Ms. Jacki Koch
Regulatory Affairs Specialist, II
3451 Plano Parkway
Lewisville, Texas 75056

Re: K162446
Trade/Device Name: FORZA Spacer System, PILLAR PEEK Spacer System, PILLAR SA PEEK 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: MAX, MQP
Dated: September 26, 2016
Received: September 28, 2016

Dear Ms. 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. 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" (21 CFR 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,

Vincent J. Devlin -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)*
K162446

Device Name
FORZA 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Indications for Use

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

510(k) Number *(if known)*
K162446

Device Name
PILLAR PEEK Spacer System

Indications for Use *(Describe)*

When used as an intervertebral body fusion device, 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 PILALR 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), 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162446

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 Spinal Fixation System (SFS).

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) 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 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162446

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.

510(k) SUMMARY

FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

510(k) Owner Information

Name: Orthofix Inc.
Address: 3451 Plano Parkway
Lewisville, TX 75056

Telephone Number: 214.937.2100
Fax Number: 214-937-3322
Email: jackikoch@orthofix.com

Registration Number: 2183449

Contact Person: Jacki Koch, Regulatory Affairs Specialist, II

Date Prepared: December 8, 2016

Name of Device

Trade Name / Proprietary Name: FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

Common Name: Spinal Vertebral Body Replacement Device
Spinal Partial Vertebral Body Replacement Device
Intervertebral Body Fusion Device

Product Code: FORZA Spacer System - MAX
PILLAR PEEK Spacer System – MAX, MQP
PILLAR SA PEEK Spacer System – MAX, MQP
SKYHAWK Lateral Interbody Fusion System - MAX

Regulatory Classification: Class II – 21 CFR § 888.3080 – Intervertebral body fusion device
Class II – 21 CFR § 888.3060 – Spinal intervertebral body fixation orthosis

Review Panel: Orthopedic Device Panel

Primary Predicate Device: FORZA Spacer System – Orthofix – K152475

Additional Predicate Devices: PILLAR PEEK Spacer System – Orthofix – K081177

ORTHOFIX

FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

	PILLAR SA PEEK Spacer System – Orthofix – K081849 SKYHAWK Lateral Interbody Fusion System – Orthofix – K140709
Reason for 510(k) Submission:	Expanded Indications for Use to include the use with allograft material composed of cancellous or corticocancellous bone graft material.

Device Description

FORZA Spacer System:

The FORZA Spacer System consists of implants, trials, and instruments. The FORZA Spacer System is comprised of a variety of implants fabricated and manufactured from polyetheretherketone (PEEK) as described by ASTM F2026 with tantalum markers as described by ASTM F560. PEEK was utilized due to its radiolucent properties, which aids the surgeon in determining if fusion is the operative site has occurred. Since PEEK is transparent in x-rays, tantalum marker pins are inserted into the implants in order to give surgeons a visual aid in determining the location of the implants, both intra and postoperatively.

PILLAR PEEK Spacer System:

The PILLAR 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 footprint sizes. Additionally, they 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 interior surfaces of the implant have a pattern of ripples to provide increased stability and help prevent anterior/posterior movement of the device.

The PILLAR 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 Spacer System is not intended to be used as a stand-alone device. The PILLAR Spacer System must be used with supplemental internal fixation. The PILLAR Spacer System is provided non-sterile.

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 footprint sizes, 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 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.

SKYHAWK Lateral Interbody Fusion System:

FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

The SKYHAWK Interbody Fusion 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 aids the surgeon in determining if fusion is the operative site has occurred. Since PEEK is transparent in x-rays, tantalum marker pins are inserted into the implants in order to give surgeons a visual aid in determining the location of the implants, both intra and postoperatively.

The SKYHAWK 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 later or anterolateral approach.

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

Indications for Use

FORZA 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.

PILLAR PEEK Spacer System:

When used as an intervertebral body fusion device, 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).

ORTHOFIX

FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

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 PILALR 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), 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 Spinal Fixation System (SFS).

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

FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

When used as a Partial Vertebral Body Replacement (VBR) 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 Spinal Fixation System (SFS).

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 of the FORZA Spacer System (K103111), PILLAR PEEK Spacer System (K082235), PILLAR SA PEEK Spacer System (K081849) and the SKYHAWK Lateral Interbody Fusion System (K140709) are all similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the FORZA Spacer System (K103111), PILLAR PEEK Spacer System (K082235), PILLAR SA PEEK Spacer System (K081849) and the SKYHAWK Lateral Interbody Fusion System (K140709) and the predicate device which would adversely affect the use of the product.

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

FORZA Spacer System
PILLAR PEEK Spacer System
PILLAR SA PEEK Spacer System
SKYHAWK Lateral Interbody Fusion System

The purpose of this 510(k) submission is to obtain clearance for the modified Indications for Use for Intervertebral Body Fusion Devices (IBFD), to include the use of allogenic bone graft composed of cancellous or corticocancellous bone graft in the spine. The subject FORZA Spacer System, PILLAR PEEK Spacer System, PILLAR SA PEEK Spacer System and the SKYHAWK Lateral Interbody Fusion System technological characteristics, design, material and principles of operation are all unchanged from when they were previously cleared.

The FORZA Spacer System Pyrogen Testing:
The FORZA Spacer System STERILE packed implants were tested using Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST-72:2011 to achieve an Endotoxin limit less than 20EU per device.

Basis of Substantial Equivalence
The FORZA Spacer System, PILLAR PEEK Spacer System, PILLAR SA PEEK Spacer System and the SKYHAWK Lateral Interbody Fusion System technological characteristics, design, material and principles of operation are all unchanged from when they were previously cleared.

Furthermore the subject devices have similar intended use, indications for use, technological characteristics, design, same materials and the same principles of operation as the to the predicate FORZA PTC Spacer System (K152475).