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

July 30, 2021

Re: K211710
Trade/Device Name: Ascent POCT System, Centurion POCT System, Spinal Fixation System (SFS), Firebird Spinal Fixation Systems: (Firebird Deformity Spinal Fixation System, Phoenix MIS Spinal Fixation System, Phoenix CDX MIS Spinal Fixation System, JANUS Midline Fixation Screws, Firebird NXG Spinal Fixation System, JANUS Fenestrated Screws), Connector System, FIREBIRD SI Fusion System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, NKB, KWP, KWQ, OUR
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,

for

Colin O'Neill, M.B.E.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Ascent POCT System

Indications for Use *(Describe)*
When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the Ascent POCT System is indicated for:
• Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
• Spondylolisthesis;
• Fracture/dislocation;
• Spinal Stenosis;
• Atlanto-axial fracture with instability;
• Occipito-cervical dislocation'
• Tumors'
• Revision of previous cervical spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) for the treatment of thoracic conditions only. They are not intended to be placed in the cervical spine. The lateral offset adapter is indicated for use in the upper thoracic spine (T1-T3). The hooks are intended to be placed from C1 to T3. The Songer Cables (titanium) System to be used with the Ascent POCT System allows for wire/cable attachment to the posterior cervical spine.

The Ascent POCT System can also be linked to the Spinal Fixation System using the axial or parallel rod connector.

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
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See PRA Statement below.

510(k) Number *(if known)*

Device Name
Centurion POCT System

Indications for Use *(Describe)*

The Centurion POCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 – T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Centurion POCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Centurion POCT System can also be linked to the Orthofix Spinal Fixation System using the Axial or Parallel Rod Connector.

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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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Connector System

Indications for Use *(Describe)*

1. When used with the Centurion POCT System or Ascent POCT System for Posterior Occipital-Cervical-Thoracic (Occ – T3) The Connector System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 – T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Connector System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

2. When used with the Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System or Spinal Fixation System (SFS) for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Ilium) The Connector System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:
1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

When used for posterior pedicle screw fixation in pediatric patients, the Connector System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach. The Connector System is intended to be used with autograft or allograft.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Spinal Fixation System (SFS)

Indications for Use *(Describe)*

The Spinal Fixation System (SFS) is intended for non-cervical use in the spine. The Spinal Fixation System (SFS), when used for pedicle screw fixation, is intended only for patients:

- Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
- Who are receiving fusion using autogenous bone graft only;
- Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
- Who are having the device removed after the development of a solid fusion mass.

The Spinal Fixation System (SFS), when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

a) Degenerative spondylolistheses with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudarthrosis)

The Spinal Fixation System (SFS), when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) Spondylolistheses;
c) Spinal stenosis;
d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) Tumor;
f) Pseudoarthrosis;
g) Previous failed fusion; and
h) Trauma (i.e., fracture or dislocation)

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180179

Device Name
Firebird Spinal Fixation Systems: Firebird Spinal Fixation System; Firebird Deformity Fixation System; Phoenix MIS Spinal Fixation System; Phoenix CDX MIS Spinal Fixation System; Firebird NXG Spinal Fixation System; JANUS Midline Fixation Screw; JANUS Fenestrated Screw

Indications for Use *(Describe)*
The Firebird Spinal Fixation Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Firebird Spinal Fixation Systems components are used with certain components of the Spinal Fixation System (SFS), including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

The Firebird Spinal Fixation Systems are intended to be used with autograft or allograft.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The JANUS Midline Fixation Screw and the JANUS Fenestrated Screw when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

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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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
FIREBIRD SI Fusion System

Indications for Use *(Describe)*
The FIREBIRD SI Fusion System is intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including;
• sacroiliac joint disruptions,
• degenerative sacroiliitis,
• to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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) SUMMARY

Ascent POCT System
Centurion POCT System
Spinal Fixation System (SFS)
Firebird Spinal Fixation Systems
which includes:
Firebird System
Firebird Deformity System
Firebird NXG Spinal Fixation System
Phoenix Minimally Invasive Spinal Fixation System
Phoenix CDX Minimally Invasive Spinal Fixation System
JANUS Midline Fixation Screw
JANUS Fenestrated Screw
Connector System
FIREBIRD SI Fusion System

510(k) Owner Information

Name:	Orthofix US LLC
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, Principle Regulatory Affairs

Date Prepared: June 2, 2021

Name of Device

Trade Name / Proprietary Name:

Ascent POCT System
Centurion POCT System
Spinal Fixation System (SFS)
Firebird Spinal Fixation Systems
- Firebird Deformity Spinal Fixation System
- Phoenix MIS Spinal Fixation System
- Phoenix CDX MIS Spinal Fixation System
- JANUS Midline Fixation Screws
- Firebird NXG Spinal Fixation System
- JANUS Fenestrated Screws

Connector System
FIREBIRD SI Fusion System

Product Code(s):

System Name	Product Codes
Ascent POCT System	KWP
Centurion POCT System	NKG, KWP
Spinal Fixation System (SFS)	NKB, KWQ, KWP
Firebird Spinal Fixation Systems • Firebird System	NKB

• Firebird Deformity System • Firebird NXG Spinal Fixation System • Phoenix Minimally Invasive Spinal Fixation System • Phoenix CDX Minimally Invasive Spinal Fixation System • JANUS Midline Fixation Screw • JANUS Fenestrated Screw	
Connector System	NKG, NKB, KWP, KWQ
FIREBIRD SI Fusion System	OUR

Classification Name(s)

System Name	Classification Name
Ascent POCT System	Spinal Interlaminal Fixation Orthosis
Centurion POCT System	Posterior Cervical Screw System
Spinal Fixation System (SFS)	Thoracolumboscacral Pedicle Screw System
Firebird Spinal Fixation Systems • Firebird System • Firebird Deformity System • Firebird NXG Spinal Fixation System • Phoenix Minimally Invasive Spinal Fixation System • Phoenix CDX Minimally Invasive Spinal Fixation System • JANUS Midline Fixation Screw JANUS Fenestrated Screw	Thoracolumboscacral Pedicle Screw Systems
Connector System	Posterior Cervical Screw System
FIREBIRD SI Fusion System	Smooth or Threaded Metallic Bone Fixation Fastener

Device Classification

System Name	Regulation
Ascent POCT System	Class II per 21 CFR § 888.3050
Centurion POCT System	Class II per 21 CFR § 888.3075
Spinal Fixation System (SFS)	Class II per 21 CFR § 888.3070
Firebird Spinal Fixation Systems • Firebird System • Firebird Deformity System • Firebird NXG Spinal Fixation System • Phoenix Minimally Invasive Spinal Fixation System • Phoenix CDX Minimally Invasive Spinal Fixation System • JANUS Midline Fixation Screw JANUS Fenestrated Screw	Class II per 21 CFR § 888.3070
Connector System	Class II per 21 CFR § 888.3075

FIREBIRD SI Fusion System	Class II per 21 CFR§ 888.3040

Review Panel: Orthopedic Device Panel

Predicate Devices:
Ascent POCT System (K111183) – Orthofix US LLC
Centurion POCT System (K201481) – Orthofix US LLC
Spinal Fixation System (SFS) (K080407) – Orthofix US LLC
Firebird Spinal Fixation Systems (K180179) – Orthofix US LLC
- Firebird Deformity Spinal Fixation System
- Phoenix MIS Spinal Fixation System
- Phoenix CDX MIS Spinal Fixation System
- JANUS Midline Fixation Screws
- Firebird NXG Spinal Fixation System
- JANUS Fenestrated Screws

Connector System (K172194) – Orthofix US LLC
FIREBIRD SI Fusion System (K210667) – Orthofix US LLC

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
Ascent POCT System - The Ascent POCT System is a temporary, multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The Ascent POCT System consists of an assortment of rods, set screws, cross connectors, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws and songer cables. When used in the occipito-cervico-thoracic spine, the Ascent POCT System may be used from the Occiput to T3.

Centurion POCT System - The Centurion POCT System is a temporary, multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome alloy that allow the surgeon to build a spinal implant construct. The Centurion POCT System consists of an assortment of rods, set screws, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and cables (titanium).

Spinal Fixation System (SFS) - The Spinal Fixation System (SFS) is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws, and hooks to the non-cervical spine. The Spinal Fixation System consists of an assortment of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, and cross-connectors. The Spinal Fixation System (SFS) titanium implants are not compatible with components or metal from any other manufacturer's system. The Spinal Fixation System (SFS) is intended for non-cervical use in the spine. When used as a non-pedicle anterolateral fixation system it may be used from levels T1 to S1. When used with pedicle screw fixation, the Spinal Fixation System (SFS) will be used at L5-S1, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 and below). When used as a posterior non-pedicle fixation system it may be used from levels T1 to S1. When used as a non-pedicle anterolateral screw fixation system to the non-cervical spine, the staple and washer may be used from levels T6-L5.

Firebird Spinal Fixation Systems: (Firebird Deformity Spinal Fixation System, Phoenix MIS Spinal Fixation System, Phoenix CDX MIS Spinal Fixation System, JANUS Midline Fixation Screws, Firebird NXG Spinal Fixation System, JANUS Fenestrated Screws)- The Firebird Spinal Fixation Systems include temporary, multiple component systems comprised of a variety of non-

sterile and sterile single use components made of titanium alloy or cobalt chrome alloy that allow the surgeon to build a spinal implant construct. The systems are attached to the vertebral body and ilium by means of screw or hook fixation to the non-cervical spine. The systems consist of an assortment of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, hooks, iliac connectors and sterile packed HA coated bone screws.

A subset of the systems' components may be used in pediatric patients. These components consist of a variety of screws ranging in diameters from 4.0mm to 7.5mm and lengths ranging from 25mm to 60mm.

Connector System - The Connector System is designed to reduce the complexity of revising and extending existing constructs from the Occiput to the Ilium. The Connector System includes a variety of non-sterile implants manufactured from titanium alloy comprised of bypass connectors, rod to rod connectors, Z rods, and an axial in-line connector with an attached rod. The Connector System implant options offered eliminate the need to remove existing hardware while providing stability to adjacent levels. The Connector System is compatible with posterior spinal fixation systems (e.g. Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System, Spinal Fixation System, Centurion POCT System, and Ascent POCT System) which offer titanium and/or cobalt chrome rods ranging in sizes of 3.0mm to 6.35mm.

FIREBIRD SI Fusion System - The FIREBIRD SI Fusion System is a temporary, multiple component system consisting of non-sterile instruments as well as both non-sterile and sterile, cannulated screws of various lengths and diameters with multiple fenestrations on their shafts. The FIREBIRD SI Screws are constructed from medical- grade titanium alloy (Ti-6Al-4V ELI). The 11mm and 12mm FIREBIRD SI Screws are 3D printed with a mid-shaft porous region. The porous titanium region has open macroscopic 3D pores with a microscopic roughened surface. The FIREBIRD SI Screw allows for packing of autograft and allograft materials.

FIREBIRD SI Fusion System consists of cannulated, fenestrated 9mm, 11mm, and 12mm diameter implants in lengths ranging from 25mm to 70mm. The 9mm diameter implant maintains a single pitch thread along the entire shaft of the implant. The 11mm diameter implant features a tapered proximal end and dual-pitch threads. The 12mm diameter implant maintains a single pitch thread form on the proximal and distal ends.

The principle of operation is based on the bone screw implants which are designed to prevent and minimize motion / micro motion of the sacroiliac (SI) joint, and thereby stabilize the joint or fracture. The mechanism of action is that the interference fit allows for fixation, stabilization and fusion.

Intended Use / Indications for Use

Ascent POCT System

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the Ascent POCT System is indicated for:

- Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Spondylolisthesis;
- Fracture/dislocation;
- Spinal Stenosis;
- Atlanto-axial fracture with instability;
- Occipito-cervical dislocation'
- Tumors'
- Revision of previous cervical spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) for the treatment of thoracic conditions only. They are not intended to be placed in the cervical spine. The lateral offset adapter is indicated for use in the upper thoracic spine (T1-T3). The hooks are intended to be

placed from C1 to T3. The Songer Cables (titanium) System to be used with the Ascent POCT System allows for wire/cable attachment to the posterior cervical spine.

The Ascent POCT System can also be linked to the Spinal Fixation System using the axial or parallel rod connector.

Centurion POCT System

The Centurion POCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Centurion POCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Centurion POCT System can also be linked to the Spinal Fixation System using the axial or parallel rod connector.

Spinal Fixation System (SFS)

The Spinal Fixation System (SFS) is intended for non-cervical use in the spine. The Spinal Fixation System (SFS), when used for pedicle screw fixation, is intended only for patients:

- Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
- Who are receiving fusion using autogenous bone graft only;
- Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
- Who are having the device removed after the development of a solid fusion mass

The Spinal Fixation System (SFS), when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

a) Degenerative spondylolistheses with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudarthrosis)

The Spinal Fixation System (SFS), when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) Spondylolistheses;
c) Spinal stenosis;
d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) Tumor;
f) Pseudoarthrosis;
g) Previous failed fusion; and
h) Trauma (i.e., fracture or dislocation)

Firebird Spinal Fixation Systems

The Firebird Spinal Fixation Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Firebird Spinal Fixation Systems components are used with certain components of the Spinal Fixation System (SFS), including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

The Firebird Spinal Fixation Systems are intended to be used with autograft or allograft.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The JANUS Midline Fixation Screw and the JANUS Fenestrated Screw when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

Connector System

1. When used with the Centurion POCT System or Ascent POCT System for Posterior Occipital-Cervical-Thoracic (Occ – T3) The Connector System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 – T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Connector System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

2. When used with the Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System or Spinal Fixation System (SFS) for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Ilium) The Connector System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

When used for posterior pedicle screw fixation in pediatric patients, the Connector System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach. The Connector System is intended to be used with autograft or allograft.

FIREBIRD SI Fusion System

The FIREBIRD SI Fusion System is intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including;

- sacroiliac joint disruptions,
- degenerative sacroiliitis,
- to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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, made of titanium alloy or cobalt chrome alloy. 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”