



May 22, 2019

Orthofix, Inc.
Ms. Jacki Koch
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K190751
Trade/Device Name: Connector System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, NKB, KWP, KWQ
Dated: March 22, 2019
Received: March 25, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K190751

Device Name

Connector System

Indications for Use (Describe)

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.

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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Indications for Use

510(k) Number (if known)
K190751

Device Name
Connector System

Indications for Use (Describe)

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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510(k) SUMMARY

Connector 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, Senior Regulatory Affairs Specialist

Date Prepared: March 22, 2019

Name of Device

Trade Name / Proprietary Name: Connector System

Common Name: 1. Posterior cervical screw system
2. Thoracolumbosacral pedicle screw system

Product Code: 1. NKG
2. NKB; KWP; KWQ

Regulatory Classification: 1. Class II – 21 CFR § 888.3075
2. Class II – 21 CFR § 888.3070; 21 CFR § 888.3050; 21 CFR § 888.

Review Panel: Orthopedic Device Panel

Predicate Devices: K172194 – Connector System - Orthofix

Reason for 510(k) Submission:

Due to the advancements in surgical techniques and surgeon requests, Orthofix is submitting this Traditional 510(k) request for the following additions and modification to the previously cleared devices listed below:

1. Addition of 16mm and 18mm Side/Front Loading Connectors
2. Addition of 16mm and 18mm Side/Side Loading Connectors
3. Addition of 16mm and 18mm Front/Front Loading Connectors
4. Addition of 16mm and 18mm Side/Top Loading Connectors
5. Addition of 16mm and 18mm Offset Z-Rod, 300mm Long
6. Addition of 16mm and 18mm Offset Z-Rod, 450mm Long
7. Modification of 12mm Side/Top Loading Connector
8. Modification of 12mm Side/Front Loading Connector
9. Modification of 12mm Side/Side Loading Connector
10. Modification of 12mm Front/Front Loading Connector

11. Modification of Small Side/Front Loading Connector
12. Modification of 16mm Bypass Connector, Left and Right
13. Modification of 34mm Bypass Connector, Left and Right
14. Modification of U-Style 16mm Bypass Connector, Left and Right
15. Modification of Axial In-Line Connector with Rod
16. Modification of 12mm Offset Z-Rod 150mm x 300mm and 150mm x 150mm

Device Description

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.

Intended Use / Indications for Use

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:

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5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
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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.

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

The technological characteristics of the subject new and modified medical devices within the previously cleared Connector System (K172194) utilize the same design, intended use, materials, and performance characteristics. There are no significant differences between the subject devices and the predicate devices which would adversely affect the use of the product.

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

Mechanical testing was conducted on the subject devices as listed below in Table 1: Mechanical Performance Testing

Table 1: Mechanical Performance Testing

Subject Device	Mechanical Performance Testing
1. Addition of 16mm and 18mm Side/Front Loading Connectors	Justification based on worst case analysis
2. Addition of 16mm and 18mm Side/Side Loading Connectors	
3. Addition of 16mm and 18mm Front/Front Loading Connectors	
4. Addition of 16mm and 18mm Side/Top Loading Connectors	
5. Addition of 16mm and 18mm Offset Z-Rod, 300mm Long	
6. Addition of 16mm and 18mm Offset Z-Rod, 450mm Long	
7. Modification of 12mm Side/Top Loading Connector	ASTM F1798 Axial Grip Testing
8. Modification of 12mm Side/Front Loading Connector	
9. Modification of 12mm Side/Side Loading Connector	
10. Modification of 12mm Front/Front Loading Connector	
11. Modification of Small Side/Front Loading Connector	
12. Modification of 16mm Bypass Connector, Left and Right	
13. Modification of 34mm Bypass Connector, Left and Right	
14. Modification of U-Style 16mm Bypass Connector, Left and Right	
15. Modification of Axial In-Line Connector with Rod	
16. Modification of 12mm Offset Z-Rod 150mm x 300mm and 150mm x 150mm	Justification - Modification is specification clarification

Basis of Substantial Equivalence

The subject new and modified medical devices within the previously cleared Connector System (K172194) are substantially equivalent to the predicate devices based upon the same intended use, indications for use, technological characteristics, design, materials and the same principles of operation.