



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

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

May 11, 2017

Re: K170647
Trade/Device Name: Connector System
Regulatory Class: Unclassified
Product Code: NKG, KWP, NKB, KWQ
Dated: March 2, 2017
Received: March 3, 2017

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170647

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)

K170647

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: May 9, 2017

Name of Device

Trade Name / Proprietary Name: Connector System

 Common Name:

1. Spinal interlaminar fixation orthosis
2. Pedicle screw spinal system

 Product Code:

1. NKG
2. NKB; KWP; KWQ

 Regulatory Classification:

1. Unclassified
2. Class II – 21 CFR § 888.3070, 21 CFR § 888.3050, and 21 CFR § 888.3060

 Review Panel: Orthopedic Device Panel

 Primary Predicate Devices:

1. K150822 – Centurion POCT System – Orthofix
2. K080407 – Spinal Fixation System – Orthofix

 Additional Predicate Devices:

K111183 – Ascent POCT System – Orthofix

 K153428 – Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System – Orthofix
 K110070 – TSRH Spinal System – Medtronic Sofamor Danek USA

 Reference Device:

K133350 – Revere Stabilization System – Globus Medical Inc.
 K130877 – EXPEDIUM Universal Connector Set - Depuy

 Reason for 510(k) Submission:



Orthofix is submitting this Traditional 510(k) premarket notification for the clearance of the Connector System.

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, 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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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 Connector System are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the subject Connector System 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
Side/Top Loading Connector with one large set screw and one small set screw	ASTM F1717, static compression bending, static torsion and dynamic compression bending
Side/Front Loading Connector with two small set screws	ASTM F1717, static compression bending, static torsion and dynamic compression bending
Small Side/Front Loading Connector with two small set screws	Cervical components, ASTM F1798 axial gripping force test
Z Rod, 150mm x 150mm	ASTM F1717, static compression bending, static torsion and dynamic compression bending

Basis of Substantial Equivalence

The subject Connector System is substantially equivalent to the predicate device based upon the indication for use, the technological characteristics, and the data submitted.