



January 22, 2018

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

Re: K180025
Trade/Device Name: Centurion POCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: January 2, 2018
Received: January 3, 2018

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.

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.

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,

 Ronald P. Jean -S for

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)

K180025

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Centurion POCT 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

Specialist Date Prepared: January 2, 2018

Name of Device

Trade Name / Proprietary Name Centurion POCT System

Common Name: Posterior, Cervical Pedicle Screw Spine Fixation
Spinal Interlaminar Fixation Orthosis Posterior
Cervical System Instrumentation

Product Code: Posterior, Cervical Pedicle Screw Spine Fixation Orthopaedic and
Rehabilitation Devices Panel Unclassified; Pre-Amendment Device
Product Code: NKG

Appliance, Fixation, Spinal Interlaminar Orthopaedic and
Rehabilitation Devices Panel
Product Code: KWP

Regulatory Classification: Unclassified

Review Panel: Orthopedic Device Panel

Primary Predicate Device: K150822 – Centurion POCT System - Orthofix

Reason for 510(k) Submission:

Orthofix is submitting this Special 510(k) request for the following modification to the previously cleared Centurion POCT System K150822:

Cross Connector – Modification to the Set Screw component to utilize a retention feature.

Device Description

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, cross connectors, parallel and axial connectors, lateral offset adapters, multi-axial screws, hooks, occipital plates, bone screws, and cables.

Intended Use / Indications for Use

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.

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

The Centurion POCT System will continue to utilize the technological characteristics in terms of design, dimensions, intended use, materials, and performance characteristics. There is no significant difference between 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

Static mechanical testing for Axial Gripping Capacity and Transverse Mechanical Property was performed per ASTM F1798-13.

Basis of Substantial Equivalence

The Centurion POCT System will continue to utilize the same intended use, indications for use, technological characteristics and design, same materials and the same principles of operation as previously cleared under K150822.