



Food and Drug Administration
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Orthofix, Incorporated
Ms. Jacki Geren
Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

May 15, 2015

Re: K150822
Trade/Device Name: Centurion POCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: March 26, 2015
Received: March 27, 2015

Dear Ms. Geren:

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.

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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 yours,

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)
K150822

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.
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Lewisville, TX 75056

Telephone Number: 214-937-2100
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Email: jackigeren@orthofix.com

Registration Number: 3008524126

Contact Person: Jacki Geren Regulatory Affairs Specialist, II

Date Prepared: March 26, 2015

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
Class 2 per 21 CFR 888.3050
Product Code: KWP

Regulatory Classification: Unclassified

Review Panel: Orthopedic Device Panel

Primary Predicate Devices: K142838 – Synapse Occipital-Cervical Thoracic (OCT)
System – Synthes USA Products, LLC

Reference Device: Centurion POCT System (K131833)

Reason for 510(k) Submission: Expanded Indications for Use

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 technological characteristics of the Centurion POCT 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 predicate device Synapse Occipital-Cervical-Thoracic (OCT) System (K142838) which would adversely affect the use of the product. The addition of the use of posterior screws in the cervical region of the spine to the Centurion POCT System (K131833) indication does not raise new types of safety and effectiveness questions (risks) not seen before. The same risks occur in the subject Centurion POCT System (K131833) as in the predicate device Synapse Occipital-Cervical-Thoracic (OCT) System (K142838).

PERFORMANCE DATA

There have been no design changes made to the Centurion POCT System (K131833) implants. The purpose of this 510(k) submission is to obtain clearance for the added indication of use of posterior screws in the cervical region of the spine to the Centurion POCT System (K131833). Published literature and mechanical testing per ASTM F1717 & F2706 (static/dynamic compression bending; static/dynamic torsion) demonstrate that the Centurion POCT System is substantially equivalent.

Basis of Substantial Equivalence

The Centurion POCT System (K131833) have the same intended use, similar indications for use, similar technological characteristics and design, same materials and the same principles of operation as the predicate device Synapse Occipital-Cervical-Thoracic (OCT) System (K142838).