510(k) Summary

Date Prepared: June 19, 2013

JAN 30 2014

Purpose for Submission: New Product Offering

Sponsor:
Orthofix Inc.
Jacki Geren
3451 Plano Parkway
Lewisville, TX 75056
214-937-2100

Device Name: Centurion POCT System

Product Code: KWP

Classification: Class II – 21 CFR §888.3050 – Spinal Interlaminal Fixation Orthosis

Predicate Device:
Ascent POCT System (K030197)
Ascent POCT System (K111183)[1]
Synthes Synapse 4.0mm System (K091689)
Biomet Spine Nextgen Altius OCT System (K122378)

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

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

a) degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
b) spondylolisthesis,
c) spinal stenosis
d) trauma (i.e., fracture or dislocation),
e) Atlanto-axial fracture with instability;
f) Occipito-cervical dislocation;
g) Tumors;
h) 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 anchoring of the OCT construct 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 cable (titanium) system to be used with the Centurion POCT System allows for wire/cable attachment to the posterior cervical spine.

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

Substantial Equivalence: The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design.

Mechanical testing demonstrates substantial equivalence of the subject components to the predicate devise in regards to mechanical strength. In addition, the intended use, packaging, and sterilization of the predicate and subject components are identical.

The subject and predicate devices are made from commercially pure titanium/ titanium alloy with the option of titanium/titanium alloy or cobalt chrome rods. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject Centurion POCT System to the predicate devices.

Testing conducted to support the substantial equivalence for the Centurion POCT System was aimed to assess static and dynamic axial compression bending and static torsion testing per:
ASTM F2706-08, "*Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*".

Additional testing of the Centurion POCT System was conducted per:

ASTM F1798 / *Static Axial Gripping Capacity / Static Axial Torque Gripping Capacity / Dynamic Axial Gripping Capacity / Dynamic Axial Torque Gripping Capacity / Static Transverse (y) Mechanical Property Test / Guidance for Industry and FDA Staff Spinal System 510(k)s May 3, 2004*

ASTM F1717, ASTM F2706 */ Static Axial Compression / Static Torsion / Dynamic Axial Compression / Dynamic Torsion / Guidance for Industry and FDA Staff Spinal System 510(k)s May 3, 2004*

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

January 30, 2014

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

Re: K131833
Trade/Device Name: Centurion POCT System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 11, 2013
Received: December 18, 2013

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Vincent D Devlin -S

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

Enclosure

510(k) Number (if known): K131833

Device Name: **Centurion POCT System**

Indications for Use:

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

a) degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies);
b) spondylolisthesis;
c) spinal stenosis;
d) trauma (i.e., fracture or dislocation);
e) atlanto-axial fracture with instability;
f) occipito-cervical dislocation;
g) tumors;
h) 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 anchoring of the OCT construct 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 cable (titanium) system to be used with the Centurion POCT System allows for wire/cable attachment to the posterior cervical spine.

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

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Zane W. Wyatt
Division of Orthopedic Devices

510(k) Number: K131833