June 15, 2020

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

Re: K201481
Trade/Device Name: Centurion POCT System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: June 3, 2020
Received: June 4, 2020

Dear Jacki 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, MBE
Acting Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201481

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

Date Prepared: June 3, 2020

Name of Device

Trade Name / Proprietary Name: Centurion POCT System

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

Product Code: NKG, KWP

Classification Name: Posterior Cervical Screw System (21 CFR 888.3075)

Regulatory Classification: II

Review Panel: Orthopedic Device Panel

Primary Predicate Devices: K180025 – Centurion POCT System – Orthofix Spine, Incorporated

Additional Predicate Device: K153631 – Zimmer Virage OCT Spinal Fixation System – Zimmer

Reason for 510(k) Submission:
Due to the advancements in surgical techniques and surgeons requests, Orthofix is submitting this **Special 510(k) premarket notification** for the addition of the below listed devices to the previously cleared devices:

1. Addition of new 3.5mm/5.5mm Transition Rods
2. Addition of new 3.5mm Occipital Rods
3. Addition of new 3.5mm Straight Rods
4. Addition of new 3.5mm Lordosed Rods

In addition, each subject device listed above will feature a longitudinal line along the length of all rods to provide better identification of induced curvature.

The subject additions to the previously cleared Centurion POCT System (K180025) do not alter the indications for use, contraindications, warnings or precautions.

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, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and cables (Titanium).

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 new subject devices are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. The new implants feature a longitudinal anodized line along their length. The new offerings include the addition of pre-cut straight rods, pre-cut lordosed rods, and a new transition rod size. There are no significant differences between the new 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
The subject devices being added to the previously cleared Centurion POCT System (K180025) specify the same rod diameter, material, surface finish, and intended use as the previously cleared devices and therefore are substantially equivalent in design and performance. There are no significant differences between the new subject devices and the predicate devices that would introduce a new worse case for performance testing. Therefore, no additional performance testing is required.

Conclusion
The technological characteristics of the subject devices being added to the Centurion POCT System have the same intended use, same indications for use, same materials, substantially equivalent design, same materials and the same principles of operation as the predicate Centurion POCT System (K180025) and Zimmer Virage OCT Spinal Fixation System (K153631). There are no significant differences between the subject devices and the previously cleared predicate device, which would adversely affect the use of the product.