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

December 16, 2016

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

Re: K162638
Trade/Device Name: CETRA Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 6, 2016
Received: December 7, 2016

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

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)*
K162638

Device Name
CETRA Anterior Cervical Plate System

Indications for Use *(Describe)*
The CETRA Anterior Cervical Plate System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:
a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spondylolisthesis;
c) Fracture;
d) Spinal Stenosis;
e) Deformities (i.e., scoliosis, kyphosis, and/or lordosis);
f) Tumor;
g) Pseudoarthrosis;
h) Revision of previous surgery

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

CETRA Anterior Cervical Plate 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, Regulatory Affairs Specialist, II

Date Prepared: September 21, 2016

Name of Device

Trade Name / Proprietary Name: CETRA Anterior Cervical Plate System

Common Name: Anterior Cervical Plate System

Product Code: KWQ

Regulatory Classification: Class II – 21 CFR § 888.3060

Review Panel: Orthopedic Device Panel

Primary Predicate: Hallmark Anterior Cervical Plate System – K100614 - Orthofix

Additional Predicates: Reliant Anterior Cervical Plate System – K030595 - Orthofix
SLIM*LOC Anterior Cervical Plate System – K013877 – Depuy Codman & Shurtleff, Inc.
MaxAn Anterior Cervical Plate System – K133518 - Biomet

Reason for 510(k) Submission: Orthofix is submitting this Traditional 510(k) premarket notification for the introduction of a new Anterior Cervical Plate System called CETRA Anterior Cervical Plate System.

Device Description

The CETRA Anterior Cervical Plate System consists of an assortment of non- sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) plates and screws that allow a surgeon to build a temporary anterior cervical implant construct. The plate is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine.

Intended Use / Indications for Use

The CETRA Anterior Cervical Plate System is intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spondylolisthesis;
c) Fracture;
d) Spinal Stenosis;
e) Deformities (i.e., scoliosis, kyphosis, and/or lordosis);
f) Tumor;
g) Pseudoarthrosis;
h) Revision of previous surgery

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

The technological characteristics of the CETRA Anterior Cervical Plate System are similar to the predicate device and reference device in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the CETRA Anterior Cervical Plate System and the predicate Hallmark Anterior Cervical Plate System (K100614) and the additional predicate devices Reliant Anterior Cervical System (K030595), SLIM*LOC Anterior Cervical Plate System (K013877) and MaxAn Anterior Cervical Plate System (K133518), which would adversely affect the use of the product.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

Mechanical testing consisting of Static Axial Compression Test, Dynamic Axial Compression Test and Static Torsion Test were conducted in accordance to ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.

Additional mechanical testing included a screw push-out test, which served to mechanically evaluate the CETRA Anterior Cervical Plate System locking mechanism's ability to retain screws after being implanted.

Conclusion

The new CETRA Anterior Cervical Plate System has the same intended use, the same indications for use, the same technological characteristics and design, same materials and the same principles of operation as the predicate Hallmark Anterior Cervical Plate System (K100614) and the additional predicate devices Reliant Anterior Cervical System (K030595), SLIM*LOC Anterior Cervical Plate System (K013877) and MaxAn Anterior Cervical Plate System (K133518).