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

May 29, 2015

Orthofix, Incorporated
Ms. Natalia Volosen
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K143028
Trade/Device Name: Azure 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: April 29, 2015
Received: April 30, 2015

Dear Ms. Volosen:

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" (21CFR 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

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)*
K143028

K143028

Device Name
Azure Anterior Cervical Plate System

Indications for Use *(Describe)*

The Azure Anterior Cervical Plate System is a temporary implant intended for anterior fixation to the cervical spine from C2 to C7 and indicated for:

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) Trauma (i.e., fracture or dislocation);
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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

K143028

Azure Anterior Cervical Plate System

510(k) Owner Information

Name:	Orthofix Inc.
Address:	3451 Plano Parkway Lewisville, TX 75056
Telephone Number:	214.937.2145
Fax Number:	214-937-3322
Email:	nataliavolosen@orthofix.com
Registration Number:	3008524126
Contact Person:	Natalia Volosen Senior Regulatory Affairs Specialist

Date Prepared:	May 14, 2015

Name of Device

Trade Name / Proprietary Name:	Azure Anterior Cervical Plate System
Common Name:	Anterior Cervical Plate System
Product Code:	KWQ - Appliance, Fixation, Spinal Intervertebral Body
Regulatory Classification:	Class II per 21 CFR § 888.3060
Review Panel:	Orthopedic Device Panel
Predicate Devices:	K130825 – Azure Anterior Cervical Plate System, SE 5/7/2013 No reference devices were used in this submission
Reason for 510(k) Submission:	Removal of constrained screws from the Azure system

Device Description

The Azure Anterior Cervical Plate System is comprised of a variety of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) with nitinol (per ASTM 2063) components that allow a surgeon to build a temporary anterior cervical implant construct. The system is attached to the anterior aspect of the vertebral body by means of screws to the cervical spine. The system consists of an assortment of screws, plates and associated instrumentation, which assists in the surgical implantation of the devices.

Intended Use / Indications for Use

The AZURE Anterior Cervical Plate System is a temporary implant, intended for anterior fixation to the cervical spine from C2 to C7 and indicated for:

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) Trauma (i.e., fracture or dislocation);
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
There are no changes in the intended use, design, specifications and / or materials of Azure Cervical Plate system. The purpose of this 510(k) submission is to remove the constrained screw configuration from the Azure Anterior Cervical Plate system.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence
A modified Dynamic Axial Compression test was conducted in accordance to ASTM F1717 standard for Azure constructs containing constrained and semi-constrained screws. The results of the modified ASTM F1717 testing show that constrained screw constructs were able to cause total fracture of the locking mechanism, similar to the failures experienced in the field. The semi-constrained screw constructs did not experience the same failure modes and therefore removing the constrained screws from the system will eliminate the risk of locking mechanism fracture.

In addition, Orthofix performed simulated testing with semi-constrained screws to validate the new recommended surgical technique (fully lagged screws or screws left above the locking mechanism).

These tests demonstrate that the Azure system containing semi-constrained screws is safe and effective for use and is substantially equivalent or better that its predicate device Azure Anterior Cervical Plate system K130825.

Basis of Substantial Equivalence
There are no changes in the intended use, design, specifications and / or materials between the subject Azure system and the Azure Cervical Plate system K130825.

The subject Azure Anterior Cervical Plate System will be as safe and effective as its predicate device Azure Anterior Cervical Plate System (K130825). Usage of constrained or semi-constrained screws is a surgeon preference based on their training and experience.