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

June 17, 2016

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

Re: K161280
Trade/Device Name: Cervical Stand Alone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: May 27, 2016
Received: May 31, 2016

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 Parts 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,

Vincent J. Devlin -S

for

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)*
K161280

Device Name
Cervical Stand Alone System

Indications for Use *(Describe)*

The Cervical Stand Alone System is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The Cervical Stand Alone System is used with autograft and /or allograft comprised of cancellous and/or corticocancellous bone graft and the two titanium alloy screws which accompany the implant.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Cervical Stand Alone System in the cervical spine.

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.

510(k) SUMMARY

Cervical Stand Alone 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 5, 2016

Name of Device

Trade Name / Proprietary Name: Cervical Stand Alone System

Common Name: Intervertebral body fusion device

Product Code: OVE – Cervical intervertebral fusion device with integrated fixation

Regulatory Classification: Class II – 21 CFR § 888.3080 – Intervertebral body fusion device

Review Panel: Orthopedic Device Panel

Predicate Devices: K142152 – Cervical Stand Alone, SE 1/8/2015
K150619 – CONSTRUX Mini PEEK Spacer, SE 9/11/2015 (reference device)

Reason for 510(k) Submission: Line extension

Device Description

Cervical Stand Alone system is designed to provide the biomechanical strength to a traditional or minimal invasive ACDF procedure with less disruption of patient anatomy and preserve the anatomical profile. The Cervical Stand Alone system helps to preserve the natural sagittal anatomic profile of the cervical spine while providing anterior column support and stability. Cervical Stand Alone is a hybrid PEEK (ASTM F-2026) and Titanium (Ti-6Al-4V) spacer which incorporates Titanium Bone Screws (Ti-6Al-4V) and a Titanium Cover Plate (Ti-6Al-4V). The Cervical Stand Alone spacers are designed with a zero anterior profile and are implanted using an anterior approach.

Intended Use / Indications for Use

The Cervical Stand Alone System is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease (DDD). DDD

is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The Cervical Stand Alone System is used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and the two titanium alloy screws which accompany the implant.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Cervical Stand Alone System in the cervical spine.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices
The technological characteristics of the modified Cervical Stand Alone System are similar to the predicate devices in terms of design, size, intended use, materials, and performance characteristics.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence
Mechanical testing consisting of Static and Dynamic Axial Compression Test, Static Torsion Test, Static Compression Shear Test, Subsidence Test and Expulsion Test were conducted in accordance to ASTM F2077-14 standard for Test Method for Intervertebral Body Fusion Devices, ASTM F2267-04 standard for Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression and in accordance with ASTM Draft Standard F-04.25.02.02, “Static Push-out Test Method for Intervertebral Body Fusion Devices.

Basis of Substantial Equivalence
The Cervical Stand Alone System has the same intended use, indications for use, technological characteristics, materials, the same principles of operation and similar design as the currently marketed Cervical Stand Alone System (K142152).