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 5, 2017

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

Re: K171082
Trade/Device Name: Firebird Spinal Fixation System, Phoenix MIS Spinal Fixation System, JANUS Midline Fixation Screw, Phoenix CDX MIS Spinal Fixation System, Firebird NXG Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: April 10, 2017
Received: April 11, 2017

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)*
K171082

Device Name
Firebird Spinal Fixation System, Phoenix MIS Spinal Fixation System, JANUS Midline Fixation Screw, Phoenix CDX MIS Spinal Fixation System, Firebird NXG Spinal Fixation System

Indications for Use *(Describe)*
The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System components are used with certain components of the Orthofix Spinal Fixation System, including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach. The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are intended to be used with autograft or allograft.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System
JANUS Midline Fixation Screw
Phoenix CDX MIS Spinal Fixation System
Firebird NXG Spinal Fixation 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
Date Prepared:	April 28, 2017

Name of Device

Trade Name / Proprietary Name:	Firebird Spinal Fixation System, Phoenix MIS Spinal Fixation System JANUS Midline Fixation Screw Phoenix CDX MIS Spinal Fixation System Firebird NXG Spinal Fixation System
Common Name:	Spinal Fixation System
Product Code:	NKB; KWP, KWQ
Regulatory Classification:	Class II - 21 CFR § 888.3070 and 21 CFR § 888.3050
Review Panel:	Orthopedic Device Panel
Primary Predicate Device:	Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K153428)
Additional Predicate:	Spinal Fixation System (K080407)

Reason for 510(k) Submission:
Orthofix is submitting this Special 510(k) request for the following medical devices which are:

1. Addition of new Reduction Body
2. Addition of new Low Profile Offset
3. Modification of the Mono-Axial Lateral Offset
4. Addition of new Front Loading and Axial Rod Connectors

5. Modification to the Top Loading Rod Connector
6. Modification to all Straight and Pre-Lordosed titanium alloy (Ti-6AL-4V ELI) Lined Rods

The above listed additions and modifications do not change the previously cleared Firebird Spinal Fixation System (K153428) indications for use, contraindications, warnings or precautions. Furthermore, the surgical approach and implantation technique remains the same as the previously cleared Firebird Spinal Fixation System (K153428).

Device Description

The Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K153428) are temporary, multiple component systems comprised of a variety of non-sterile and sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The systems are attached to the vertebral body and ilium by means of screw or hook fixation to the non-cervical spine. The Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System consist of an assortment of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, hooks, iliac connectors and STERILE packed HA Coated bone screws. A subset of the Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System components may be used in pediatric patients. These components consist of a variety of screws ranging in diameters from 4.0mm to 7.5mm and lengths ranging from 25mm to 60mm.

Intended Use / Indications for Use

The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System components are used with certain components of the Orthofix Spinal Fixation System, including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior

approach. The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are intended to be used with autograft or allograft.

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

The technological characteristics of the subject devices are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the subject devices and the predicate device Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K153428) which would adversely affect the use of the product.

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

Mechanical testing was conducted on the subject devices as listed below in Table 1: Mechanical Performance Testing

Table 1: Mechanical Performance Testing

Subject Device	Mechanical Testing
Reduction Body	Dynamic Compression Bending per ASTM F1717-15
Low Profile Offset	Justification based upon worst case Mono-Axial Lateral Offset construct
Mono-Axial Lateral Offset	Dynamic Compression Bending per ASTM F1717-15
Front Loading, Top Loading & Axial Rod Connectors	Dynamic Compression Bending per ASTM F1717-15
Anodized Straight and Pre-Lordosed titanium alloy (Ti-6AL-4V ELI) Lined Rods	Dynamic Compression Bending per ASTM F1717-15

Basis of Substantial Equivalence

The performance and technological characteristics of the subject devices are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the subject devices and the predicate device Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K153428) which would adversely affect the use of the product.