DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 29, 2016

Orthofix, Incorporated
Ms. Jacki Geren
Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K153428
Trade/Device Name: Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP
Dated: November 24, 2015
Received: November 25, 2015

Dear Ms. Geren:

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 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" (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 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)*
K153428

Device Name
Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System

Indications for Use *(Describe)*
The Firebird Spinal Fixation System and Phoenix MIS Spinal Fixation System are intended for posterior, non-cervical pedicle, and non-pedicle fixation (T1-S2/Ilium). Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

a) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
b) spondylolisthesis,
c) trauma (i.e., fracture or dislocation),
d) spinal stenosis,
e) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
f) tumor,
g) pseudoarthrosis, and
h) 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 non-cervical pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Firebird Spinal Fixation System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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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510(k) SUMMARY

Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System

510(k) Owner Information

Name:	Orthofix Inc.
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Fax Number:	214-937-3322
Email:	jackigeren@orthofix.com

Registration Number:	3008524126
Contact Person:	Jacki Geren, Regulatory Affairs Specialist, II
Date Prepared:	November 24, 2015

Name of Device

Trade Name / Proprietary Name:	Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System
Common Name:	Spinal Fixation System
Product Code:	NKB; OSH; KWP; MNH; MNI
Regulatory Classification:	Class III Pre amendment Device, 21 CFR §888.3070 – Pedicle screw spinal system
Review Panel:	Orthopedic Device Panel
Primary Predicate:	Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K130932)
Additional Predicates:	Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K151488) Spinal Fixation System (K023498)

Reason for 510(k) Submission:
Orthofix is submitting this Traditional 510(k) premarket notification for the addition of the below to the previously cleared Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K151488):

- JANUS Midline Fixation Screw (Cannulated and Non-Cannulated)
- Phoenix CDX MIS Spinal Fixation System – Modular Mono-Axial Body with Extended Tab
- Firebird NXG Spinal Fixation System –

  - Set Screw
  - Multi-Axial Screw Top-Loading Body
  - Low Profile Off-Set Body
- Modified Firebird Spinal Fixation System Bone Screws

Device Description
The Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K151488, K130932) 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 for posterior, non-cervical pedicle, and non-pedicle fixation (T1-S2/Ilium). Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

a) degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
b) spondylolisthesis,
c) trauma (i.e., fracture or dislocation),
d) spinal stenosis,
e) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
f) tumor,
g) pseudoarthrosis, and
h) 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 non-cervical pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Firebird Spinal Fixation System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices
The technological characteristics of the subject devices presented in Table 1: Technological Characteristics 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 (K130932) which would adversely affect the use of the product.

Table 1: Technological Characteristics

	Subject Device: Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System JANUS Midline Fixation Screw Phoenix CDX MIS Spinal Fixation System Firebird NXG Spinal Fixation System	**Primary Predicate Device: Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K130932)**
Device Name	Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System JANUS Midline Fixation Bone Screw Phoenix CDX MIS Spinal Fixation System Firebird NXG Spinal Fixation System	Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K130932)
Method of Fixation	Non-Cervical Fixation	Non-Cervical Fixation
Implantation	Posterior Approach	Posterior Approach
Design	This system allows a surgeon to build a spinal implant construct	This system allows a surgeon to build a spinal implant construct
Material	Titanium alloy (Ti-6AL-4V ELI)	Titanium Alloy (Ti-6AL-4V ELI)

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 2: Mechanical Performance Testing

Table 2: Mechanical Performance Testing

Subject Device	**Mechanical Testing**
JANUS Midline Fixation Screw (Cannulated and Non-Cannulated)	Insertion Torque Mechanical Testing (Non-Cannulated)
Phoenix CDX MIS Spinal Fixation System Modular Mono-Axial Body with Extended Tab	Flexion-Bending tests per ASTM F1798-13 “Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants”. Static and Dynamic Compression Bending and Static Torsion tests per ASTM F1717-14 "Standard Test Mehods for Spinal Implant Constructs in a Vertebrectomy Model."
Firebird NXG Spinal	Static and Dynamic Compression Bending and

Fixation System: • Set Screw • Multi-Axial Screw Top-Loading Body • Low Profile Offset Body and Set Screw	Static Torsion tests per ASTM F1717-14 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model."
Modified Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System Bone Screws	No mechanical testing performed. Modification entailed increasing thread surface area at the distal tip of the bone screw with no changes to the structural integrity of the main threaded section or neck of the bone screw.

Basis of Substantial Equivalence

The subject devices will utilize the same intended use, indications for use, and will have the same technological characteristics, design, materials and principles of operation as to the predicate Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System (K130932).