August 24, 2018

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

Re: K180179
Trade/Device Name: Firebird® Spinal Fixation Systems: Firebird System; Firebird Deformity System; Firebird® NXG Spinal Fixation System; Phoenix® Minimally Invasive Spinal Fixation System; Phoenix® CDX™ Minimally Invasive Spinal Fixation System; JANUS® Midline Fixation Screw; JANUS® Fenestrated Screw
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 23, 2018
Received: July 24, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180179

Device Name
Firebird® Spinal Fixation Systems: Firebird System; Firebird Deformity System; Firebird® NXG Spinal Fixation System; Phoenix® Minimally Invasive Spinal Fixation System; Phoenix® CDX™ Minimally Invasive Spinal Fixation System; JANUS® Midline Fixation Screw; JANUS® Fenestrated Screw

Indications for Use *(Describe)*
The Firebird Spinal Fixation Systems 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 Firebird Spinal Fixation Systems components are used with certain components of the Spinal Fixation System (SFS), including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation Systems 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 Systems are intended to be used with autograft or allograft.

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

The JANUS Midline Fixation Screw and the JANUS Fenestrated Screw when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

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 Systems:
JANUS Fenestrated Screws

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: July 23, 2018

Name of Device

Trade Name / Proprietary Name: Firebird® Spinal Fixation System which includes:
Firebird System
Firebird Deformity System
Firebird® NXG Spinal Fixation System
Phoenix® Minimally Invasive Spinal Fixation System
Phoenix® CDX™ Minimally Invasive Spinal Fixation System
JANUS® Midline Fixation Screw
JANUS® Fenestrated Screw

Common Name: Spinal Fixation System

Product Code: NKB

Regulatory Classification: Class II – 21 CFR § 888.3070 – Thoracolumbosacral Pedicle Screw System

Review Panel: Orthopedic Device Panel

Predicate Devices: Firebird Spinal Fixation System – Orthofix Inc – K171082

Additional Predicate Device: VIPER and EXPEDIUM Fenestrated Screw Systems - DePuy Spine, Inc. - (K160879)

Reason for 510(k) Submission:
Due to the advancements in surgical techniques and surgeon requests, Orthofix is submitting this Traditional 510(k) premarket notification for the addition of the JANUS Fenestrated Screws.

Device Description

The Firebird Spinal Fixation Systems include 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 systems 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 systems' 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.

The JANUS Fenestrated Screws are a family of modular, cannulated bone screws manufactured from Ti-6AL-4V ELI or Ti-6AL-4V ELI with HA (Hydroxyapatite) Coating that features a fenestrated distal end. The JANUS Fenestrated Screws are designed to be used in an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

Intended Use / Indications for Use
The Firebird Spinal Fixation Systems 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 Firebird Spinal Fixation Systems components are used with certain components of the Spinal Fixation System (SFS), including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation Systems 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 Systems are intended to be used with autograft or allograft.

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

The JANUS Midline Fixation Screw and the JANUS Fenestrated Screw when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

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

The technological characteristics of the JANUS Fenestrated Screws are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the JANUS Fenestrated Screws and the predicate devices 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 JANUS Fenestrated Screws as listed in Table 1: Mechanical Performance Testing.

Table 1: Mechanical Performance Testing

Subject Device	Mechanical Testing
4.5mm X 35mm JANUS HA Coated Fenestrated Screw	ASTM F543, Annex A2: Test Method for Driving Toque of Medical Bone Screws
4.5mm X 30mm JANUS Fenestrated Screw	JANUS Fenestrated Screw Worst Case Rationale Justification Memo (10116202)

Engineering analysis compared the bone screw shank geometry and strength of the worst case JANUS Fenestrated Screw (4.5mmx30mm) with the worst case predicate Firebird Spinal Fixation System Screw, K171082 (4.5mmx20mm). Based on the analysis, it is concluded that the subject JANUS Fenestrated Screw does not present a new worst case in terms of mechanical strength under torsion and bending load.

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

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 devices.