510(k) Summary

Submitter:

Orthofix, Inc.
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Lewisville, TX 75056

Contact:

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AUG 07 2013

Date Prepared: April 2, 2013

Prepared By:

Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
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Product Code(s): NKB; OSH; KWP; MNH; MNI

Classification Name: Pedicle screw spinal system

Device Class: Class III Preamendment Device, 21 CFR §888.3070 – *Pedicle screw spinal system* - *Class III Summary and Certification Required

Classification Panel: Orthopedic

Proprietary Name: Firebird Spinal Fixation System

Device Description: The Firebird Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body and ilium by means of screw or hook fixation to the non-cervical spine. The Firebird Spinal Fixation System consists of an assortment of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, hooks and iliac connectors.

The expansion of indications for the Firebird Spinal Fixation System is proposed for the inclusion of adolescent idiopathic scoliosis alone, and not other indications for a pediatric population.

A subset of the Firebird Spinal Fixation System and Phoenix MIS System components may be used in pediatric patients. These components consist of a variety of screws ranging in diameters from 4.5mm to 7.5mm and lengths ranging from 25mm to 60mm.

Indications For Use:

The Firebird Spinal Fixation System is 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:

- degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis,
- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis, and
- 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 Spinal 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 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.

Materials:

Titanium alloy per ASTM F136 and Cobalt-Chrome per ASTM F1537.

Predicate Devices:

The Firebird Spinal Fixation System is substantially equivalent to the predicate devices:

K081684, K082797, K100044, K093926 and K122901- Firebird Spinal Fixation System manufactured by Orthofix Inc.

K113666-XIA III Spinal System manufactured by Stryker Spine

K091445-CD HORIZON Spinal System manufactured by Medtronic Sofamor Danek USA

K994121-USS Small Stature manufactured by Synthes Spine

K121630- Range Spinal System manufactured by K2M, Inc.

K111492-TSRH Spinal System manufactured by Medtronic Sofamor Danek USA

The design features, material and indications for use of the Firebird Spinal Fixation System are substantially equivalent to the XIA III (K113666), CD Horizon Spinal System (K091445), USS Small Stature (K994121), Range Spinal System (K121630), and the TSRH Spinal System (K111492). The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design.

Performance Data:

Previous testing performed on this device indicates that the Firebird Spinal Fixation System is substantially equivalent to predicate devices. Previous mechanical testing of the system included static and dynamic compression bending testing and static torsion testing per ASTM F1717-04 and finite element analysis. Published clinical results and engineering analysis supported expansion of indications.

Conclusion:

The Firebird Spinal Fixation System is shown to be substantially equivalent to previously cleared devices with respect to intended use, design, function, materials, and performance.

The Firebird Spinal Fixation System has the same technological characteristics, materials and intended use as the predicate devices.

Design: The subject Firebird Spinal Fixation System and the predicate devices are designed for posterior fixation from T1 to S2/Ilium using a posterior approach.

Materials: The subject Firebird Spinal Fixation System and the predicate devices are all manufactured with titanium alloy (Ti6al4V ELI per ASTM F136) or cobalt chrome (per ASTM F1537)

The subject Firebird Spinal Fixation System and the predicate devices (all system rods) are manufactured with the option of titanium alloy (Ti6al4V ELI per ASTM F136) or Cobalt Chrome (per ASTM F1537).

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

August 7, 2013

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

Re: K130932
Trade/Device Name: Firebird 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: July 03, 2013
Received: July 08, 2013

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 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use

510(k) Number (if known): K130932

Device Name: **Firebird Spinal Fixation** System

The Firebird Spinal Fixation System is 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:

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The Firebird 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.

Prescription Use ___X___	AND/OR	Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130932