K140260
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5.0 510(k) Summary

JUL 02 2014

Date Prepared: May 30, 2014

Purpose for Submission: New product offering

Sponsor:
Orthofix
Troy Brooks, RAC
3451 Plano Parkway
Lewisville, Texas 75056
214-937-2047

Device Name: SKYHAWK™ Lateral Plate System

Product Code: KWQ

Classification: Class II – 21 CFR§ 888.3060 – Spinal Intervertebral Body Fixation Orthosis

Predicate Device:
Blackstone Medical Spinal Fixation System (SFS) - K080407
Blackstone Medical Spinal Fixation System (SFS) - K023498
NuVasive Lateral Plate System - K091071
NuVasive Lateral Plate System - K061789
Globus Medical Plymouth Thoracolumbar Plate System - K120092

Device Description: The SKYHAWK Lateral Plate System consists of an assortment of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) rigid plates, bone screws, and set screws. The plates attach by means of screws to the anterolateral or lateral portion of the vertebral body of the thoracolumbar spine (T1-L5). The system includes instrumentation which assists in the surgical implantation of the devices. The SKYHAWK Lateral Plate System implants and instruments are provided non-sterile. They require sterilization prior to use.

Intended Use: The SKYHAWK Lateral Plate System is intended to be used as a non-pedicle lateral or anterolateral fixation system in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1 to L5 with the following indications:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Spondylolisthesis;
- Spinal stenosis;
- Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis;
- Failed previous fusion; and
- Trauma (i.e., fracture or dislocation).

Non-Clinical Testing: Mechanical testing of the SKYHAWK Lateral Plate System consisting of static and dynamic axial compression bending testing and static torsion testing was conducted in accordance with ASTM F1717-13 *"Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model."* Test

results demonstrate that the SKYHAWK Lateral Plate System performs as well or better than the predicate device and is therefore substantially equivalent to the predicate device.

Conclusion: Based upon similarities in design, materials, intended use, indications for use and the results of mechanical testing, the SKYHAWK Lateral Plate System is substantially equivalent to the predicate devices.

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

July 2, 2014

Orthofix, Incorporated
Troy Brooks, RAC
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K140260
Trade/Device Name: SKYHAWK™ Lateral Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 30, 2014
Received: June 2, 2014

Dear Mr. Brooks:

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 yours,

Ronald P. Jean -S for

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

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K140260

Device Name: **SKYHAWK™ Lateral Plate System**

Indications for Use:

The SKYHAWK Lateral Plate System is intended to be used as a non-pedicle lateral or anterolateral fixation system in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1 to L5 with the following indications:

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- Pseudoarthrosis;
- Failed previous fusion; and
- Trauma (i.e., fracture or dislocation).

Prescription Use X (Per 21 CFR 801.109)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices