FEB - 4 2010

510(k) SUMMARY

Spinal Fixation System Modification – Side-loading Body

Sponsor:	Blackstone Medical, Inc. 1211 Hamburg Turnpike Suite 300 Wayne, NJ 07470
Registration Number:	3004606875
Contact Person:	Whitney G. Törning, Senior Director of Regulatory Affairs & Quality Assurance
Telephone Number:	973.406.2838
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Submitter:	Martin G. Sprunck. Regulatory Affairs Manager
Manufacturer:	Orthofix, Inc. 1720 Bray Central Dr. McKinney, TX 75069
Registration Number:	2183449
Contract Manufacturer:	Structure Medical, Inc. 2975 S. Horseshoe Drive Naples, Florida 34104
System Name:	Firebird Spinal Fixation System
Trade Name (Component):	Firebird Side-loading Body
Common Name (System):	Posterior Thoracolumbar System
Product Code:	NKB – Orthosis, Spinal Pedicle Fixation, for Degenerative Disc Disease
Subsequent Product Codes:	MNI – Orthosis, Spinal Pedicle Fixation MNH – Orthosis, Spondylolisthesis Spinal Fixation

Regulatory Classifications:	Class III Preamendment Device, 888.3070 – *Pedicle Screw Spinal System* - *Class III Summary and Certification Required Class II – 888.3070 – *Pedicle Screw Spinal System*
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Blackstone Pedicle Screw System (K081684 SE 9/15/08) Blackstone Pedicle Screw System, 4.0 mm Screws (K082797 SE 10/17/08) Firebird Spinal Fixation System, Cobalt-Chrome Rods (K092624 SE 9/25/09) Blackstone Spinal Fixation System (K080407 SE 3-13-08) Synthes Universal Spine System (USS) (K082572 SE 11-24-08)

Intended Use / Indications for Use

The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle fixation. 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:

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

The Firebird Spinal Fixation Screw System components are used with certain components of the Blackstone SFS system, including rods, rod connectors and cross-connectors.

Technological Characteristics

The Firebird Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws to the non-cervical spine. The spinal construct is completed by connecting the screws with titanium alloy or cobalt chrome rods.

Performance Data

Mechanical testing of the Firebird Spinal Fixation system with the Side-loading Body was conducted in accord with ASTM standards, and demonstrates that the system is substantially equivalent to predicate systems. The additional component does not change the intended use, indications, technological characteristics or principles of operation of the Firebird Spinal Fixation System.

Basis of Substantial Equivalence

Mechanical testing was conducted to demonstrate that the Firebird Spinal Fixation System with the addition of the Side-loading Body is substantially equivalent to the current Firebird Spinal Fixation System, (K081684 SE 9/15/08, K082797 SE 10/17/08 and K092624 SE 9/25/09), which has been cleared by FDA for the purpose of building a spinal implant construct in the non-cervical spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB - 4 2010

Blackstone Medical, Inc.
% Ms. Whitney G. Törning
Senior Director of Regulatory Affairs
and Quality Assurance
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

Re: K100044
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, MNH, MNI
Dated: January 07, 2010
Received: January 08, 2010

Dear Ms. Törning:

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.

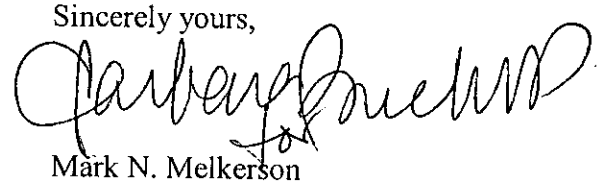
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K100044

System Name: Firebird Spinal Fixation System
Device Name: Firebird Side-loading Body

Indications for Use:

The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle fixation. 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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Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100044