510(k) SUMMARY

Blackstone Medical, Inc. Expanded Firebird Spinal Fixation System

Date:	7-23-2010
Sponsor:	Blackstone Medical, Inc. 1211 Hamburg Turnpike Suite 300 Wayne, NJ 07470
Registration Number:	3004606875
Contact Person:	Russell Johnson Regulatory Affairs
Telephone Number: Fax Number: Email:	214-937-2000 800-445-1923 russelljohnson@orthofix.com
Submitter:	Martin G. Sprunck Regulatory Affairs Manager
Manufacturer:	Orthofix, Inc. 1720 Bray Central Dr. McKinney, TX 75069
Registration Number:	2183449
Contract Manufacturers:	Pulse Technologies 2000 AM Drive Quakertown, PA 18951 Structure Medical, Inc. 2975 S. Horseshoe Dr., Suite 400 Naples, FL 34104 Accellent, Inc. 6500 Zane Avenue North, Suite 105 Brooklyn Park, MN 55429

JUL 2 8 2010

Trade Name:	Firebird Spinal Fixation 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 KWP – Appliance, Fixation, Spinal Interlaminal
Common Name:	Posterior Thoracolumbar/Iliosacral System
Regulatory Classification:	Class III preamendment Device, 888.3070 – *Pedicle Screw Spinal System* - *Class III Summary and Certification Required Class II – 888.3070 – *Pedicle Screw Spinal System* Class II – 888.3050 - *Spinal Interlaminal Fixation Orthosis*
Review Panel:	Orthopedic Device Panel

Predicate Devices:

- Firebird Spinal Fixation System, Cobalt-Chrome Rods (K092624 SE 9-25-09)
- Blackstone Pedicle Screw System, 4.0 mm Screws (K082797 SE 10-17-08)
- Blackstone Pedicle Screw System (K081684 SE 9-15-08)
- Blackstone Medical, Inc. Spinal Fixation System (SFS), represented by that system's most recent premarket notification, K080407 SE 3-13-08
- Synthes Universal Spine System Iliosacral/Polyaxial System (K082572 SE 11-24-08)
- DePuy Acromed Moss Miami Spinal System (K030383 SE 2-26-2010)
- DePuy Acromed Isola System (K993030 SE 12/29/1999)
- DePuy Acromed Monarch Spine System (K024348 SE 1/28/2003)

Intended Use / Indications for Use

The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle, and non-pedicle fixation (T1-S2/Ilium). The system is limited to use in 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

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 System components are used with certain components of the SFS system, including rod connectors and cross-connectors.

Technological Characteristics

The additional, non-pedicle components presented in this premarket notification consist of Hooks and Iliac Connectors.

Performance Data

Evaluations of the proposed components for addition to the Firebird Spinal Fixation System were conducted and demonstrate that the expanded system is substantially equivalent to predicate devices that have the same intended use, similar indications, technological characteristics and principles of operation.
Static compression bending, static torsion, and dynamic compression bending were conducted and results were compared to the predicate Firebird systems when used for the same intended use of iliac fixation.

Substantial Equivalence

The expanded Firebird Spinal Fixation System and its predicate systems have the same intended use and similar indications, technological characteristics and principles of operation. The only technological differences between the proposed component and their predicates are technical characteristics that have been addressed by mechanical evaluations. These differences do not present any new issues of safety or effectiveness, therefore, the expanded system is substantially equivalent to its predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 28 2010

Blackstone Medical, Inc.
% Mr. Russell Johnson
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

Re: K093926
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, MNI, MNH, KWP
Dated: July 07, 2010
Received: July 08, 2010

Dear Mr. Johnson:

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

K093926

Indications for Use Statement

510(k) Number (if known): K093926

JUL 2 8 2010

System Name: Firebird Spinal Fixation System
Device Name: Non-Pedicle Components

Indications for Use:

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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 K093926