K092624

SEP 2 5 2009

510(k) SUMMARY

Spinal Fixation System Modification – Cobalt Chrome Rod

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
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Submitter:	Martin G. Sprunck Regulatory Affairs Manager
Manufacturer:	Blackstone Medical, Inc. 1211 Hamburg Turnpike, Ste. 300 Wayne, NJ 07470
Registration Number:	3004606875
Contract Manufacturer:	Precision Forms, Inc. 97 Decker Rd. Butler, NJ 07405
System Name:	Firebird Spinal Fixation System
Trade Name (Component):	Firebird Cobalt Chrome Rod
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) K2M, Inc. CoCr Rod (K080792 SE 4-8-08) Applied Spine Technologies, Inc. Bar Pedicle Screw Spinal Fixation System (K061162 SE 7-26-06)

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 cobalt chrome rods was conducted in accord with ASTM standards, and demonstrates that the system is substantially equivalent to the predicate system when using titanium alloy rods. The modified system has the same intended use, similar indications, technological characteristics and principles of operation as the predicate system.

Basis of Substantial Equivalence

Mechanical testing was conducted to demonstrate that the Firebird Spinal Fixation System with the addition of cobalt chrome alloy rods is substantially equivalent to the current Firebird Spinal Fixation System, (K081684 SE 9/15/08 and K082797 SE 10/17/08), 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 2 5 2009

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

Re: K092624
Trade/Device Name: Firebird Spinal Fixation System, Firebird Cobalt Chrome Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: August 24, 2009
Received: August 26, 2009

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.

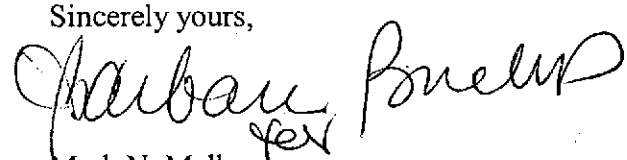
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (240) 276-3150 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):_____

System Name: Firebird Spinal Fixation System
Device Name: Firebird Cobalt Chrome Rods

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)

Koreen S. Bunney for M&M
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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