K080407

510(K) SUMMARY

Name of Firm: Blackstone Medical, Inc.
1211 Hamburg Turnpike
Wayne, NJ 07470

MAR 13 2008

510(k) Contact: Whitney Törning, Senior Director of Regulatory Affairs and Quality Assurance

Trade Name: Blackstone SFS Parallel Rod Connectors

Common Name: Rod and screw spinal instrumentation

Device Product Code & Classification:
KWP – 888.3050 – Spinal Interlaminal Fixation Orthosis
KWQ – 888.3060 – Spinal Intervertebral Body Fixation Orthosis
MNH - 888.3070 – Spondylolisthesis Spinal Fixation Device System
MNI – 888.3070 – Pedicle Screw Spinal System

Substantially Equivalent Devices:

Blackstone™ SFS (K994217 SE 2-28-00)
Blackstone™ SFS 4.5mm Multi-Axial Screws (K020674 SE 4-3-02)
Blackstone™ SFS 4.5mm Mono-Axial Screws (K013558 SE 1-23-02)
Blackstone™ SFS 2nd Gen. Cross-Connector (K003735 SE 5-8-01)
Blackstone™ SFS Modified Multi-Axial Screws (K023498 SE 11-13-02)
Blackstone™ SFS Hooks (K013885 SE 2-1-02)
Blackstone™ SFS Spacers (K022399 SE 8-6-02)
Blackstone™ SFS Staple & Washer (K022605 SE 8-21-02)
Blackstone™ SFS Axial Domino (K030241 SE 2-21-03)
Blackstone™ SFS Rigid Cross Connector (K030862 SE 4-17-03)
Blackstone™ SFS Lateral Offset (K030581 SE 6-26-03)

Device Description:

The Blackstone Spinal Fixation System (SFS) is comprised of titanium alloy (Ti-6AL-4V ELI per ASTM F136) devices in a variety of non-sterile, single-use components. This system allows a surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws and hooks to the non-cervical spine.

The SFS Parallel Rod Connectors will function as rod connectors. They are fabricated of titanium alloy (Ti-6AL-4V) and are provided in both top-loading and front-loading configurations. Both configurations allow for rod components to be connected side-to-side, rather than end-to-end, as with the currently marketed Blackstone SFS Axial Domino (Connector) (K030241 SE 2-21-03).

Intended Use / Indications for Use:

The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. The Blackstone Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients:

a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The Blackstone Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

a) Degenerative spondylolistheses with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudarthrosis).

The Blackstone Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation)

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Basis of Substantial Equivalence:

Mechanical testing was conducted to demonstrate that the Blackstone Spinal Fixation System Parallel Rod Connectors are substantially equivalent to the Blackstone™ Spinal Fixation System (K994217 SE 2-28-00), and Blackstone™ SFS Axial Domino (K030241 SE 2-21-03) which have 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
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

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

Re: K080407
Trade/Device Name: Blackstone™ Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWQ, KWP
Dated: February 12, 2008
Received: February 14, 2008

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080407

Device Name: Blackstone™ Spinal Fixation System

Indications for Use:

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e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

Neil R. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080407

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The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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