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MAY - 8 2001

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Firm:	Blackstone Medical, Inc. 90 Brookdale Drive Springfield, MA 01104
510(k) Contact:	Alan Lombardo Director of Engineering
Trade Name:	Blackstone™ Spinal Fixation System Second-Generation Cross-Connector
Common Name:	Rod and screw spinal instrumentation
Device Product Code & Classification:	**MNH** 888.3070 - Spondylolisthesis Spinal Fixation Device System **KWQ** 888.3060 - Spinal Intervertebral Body Fixation Orthosis **MNI** 888.3070 – Pedicle Screw Spinal System
Substantially Equivalent Devices:	Blackstone™ Spinal Fixation System (K994217)

Device Description:

The Blackstone™ Spinal Fixation System Second-Generation Cross-Connector is a 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 Blackstone™ Spinal Fixation System Second-Generation Cross-Connector is a new cross-connector device with various sizes. This device is an addition to the current system (K994217) and therefore is fully cross-functional within the current system.

Intended Use / Indications for Use:

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 spondylolisthesis 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 fixation, is intended for the following indications:
a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
b) Spinal stenosis;
c) Spondylolisthesis;
d) Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
e) Pseudarthrosis;
f) Tumor;
g) Trauma (i.e., fracture or dislocation);
h) Previous failed fusion.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Blackstone™ Second-Generation Cross-Connector by its very nature is substantially equivalent to the Blackstone™ Spinal Fixation System Cross-Connector which has been cleared by FDA for certain anterior and pedicle fixation use indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Mr. Alan Lombardo
Director, Engineering
Blackstone Medical, Inc.
90 Brooksdale Drive
Springfield, Massachusetts 01104

Re: K003735
Trade Name: Blackstone™ Spinal Fixation System Second-Generation Cross-Connector
Regulation Number: 21 CFR 888.3050 and 21 CFR 888.3070
Regulatory Class: Class II
Product Code: MNI, MNH and KWQ
Dated:
Received: March 19, 2001

Dear Mr. Lombardo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003735

Device Name: *Blackstone™ Spinal Fixation System*

Indications for Use:

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.

(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

510(k) Number K003735

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 spondylolisthesis 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 fixation, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies);
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c) Spondylolisthesis;
d) Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis);
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