K022399 p 1/3

AUG 0 6 2002

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 Spacer (System Modification)
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) Blackstone™ Spinal Fixation System Second-Gen Cross-Connector (K003735) Blackstone™ Spinal Fixation System 4.5mm Mono-Axial Screws (K013558) Blackstone™ Spinal Fixation System 4.5mm Multi-Axial Screws (K020674)

Device Description:

The Blackstone™ Spinal Fixation System Spacer (System Modification) is a titanium alloy (6AL-4V ELI, per ASTM F136) device, which is a non-sterile, single use component. This device is an adjunct to the Spinal Fixation System, which allows a surgeon to build a spinal implant construct. The system's design is intended to stabilize the spinal operative site during the fusion process of a bone graft in the disc space. The device added to the current Spinal Fixation System is listed below with a brief description.

Spacer:

The Spacer is available in one diameter and two thicknesses. This device may be required in various clinical applications, as determined by a qualified surgeon. The Spacer has a spherical recess feature, which allows the head of a pedicle screw to nest in it for congruent contact between components. For the actual application of the device

refer to the surgical technique in Appendix A, Exhibit D.

The Spacer is available in the configurations are as follows:

Spacer 3mm thickness
Spacer 5mm thickness

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™ Spacer is a system modification to the Blackstone™ Spinal Fixation System which has received regulatory clearance as follows:

Blackstone™ Spinal Fixation System (K994217)
Blackstone™ Spinal Fixation System Second-Gen Cross-Connector (K003735)
Blackstone™ Spinal Fixation System 4.5mm Mono-Axial Screws (K013558)
Blackstone™ Spinal Fixation System 4.5mm Multi-Axial Screws (K020674)

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

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

Re: K022399
Trade/Device Name: Blackstone Spinal Fixation System Spacer
Regulation Number: 21 CFR 888.3060, 888.3070
Regulation Name: Spinal intervetebral body fixation orthosis; spondylolisthesis spinal fixation device system; pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWQ, MNH, MNI
Dated: July 22, 2002
Received: July 23, 2002

Dear Mr. Lombardo:

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

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

Indications for Use: K022399

Blackstone Spinal Fixation System is intended for non-cervical use in the spine.

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e) Pseudarthrosis;
f) Tumor;
g) Trauma (i.e., fracture or dislocation);
h) Previous failed fusion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

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

510(k) Number K022399