OCT - 9 2003

510(K) SUMMARY

Name of Firm:	Blackstone Medical, Inc. 90 Brookdale Drive Springfield, MA 01104
510(k) Contact:	Dean E. Ciporkin Director, Regulatory Affairs and Quality Assurance
Trade Name:	Blackstone™ Surgical Titanium Mesh System Angled End Rings
Common Name:	Spinal Vertebral Body Replacement Device
Device Product Code & Classification:	**MQP**– 888.3060 – Spinal Vertebral Body Replacement Device
Substantially Equivalent Device:	Blackstone Surgical Titanium Mesh System (K030744)

Device Description:

The Blackstone Medical, Inc. Surgical Titanium Mesh System is comprised of a hollow cylindrical tube made from commercially pure (CP) titanium conforming to ASTM F-67. The walls of the tube are perforated with evenly spaced diamond-shaped openings. These openings and the hollow core allow grafting material to be placed inside the device to help achieve solid fusion. Because of the construction, the angle and the length of the mesh can be reduced incrementally to adjust it to individual anatomical conditions. The end rings, standard ring and screws of the device are made of titanium alloy (6AL-4V ELI, per ASTM F136). The end rings, which are placed onto each end of the tube, feature spikes on the exterior sides that help prevent lateral movement of the device.

Intended Use / Indications for Use:

The Blackstone Medical Surgical Titanium Mesh System is indicated for use in the thoraco-lumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Surgical Titanium mesh is also indicated for treating fractures of the thoracic and lumbar spine.

The Surgical Titanium Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. It is recommended to pack bone graft material inside the mesh cage prior to implantation.

The Surgical Titanium Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation system that may be used with the Surgical Titanium Mesh System is the Blackstone Medical Spinal Fixation System.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Blackstone™ Surgical Titanium Mesh System Angled End Rings are substantially equivalent to the Blackstone Surgical Titanium Mesh System (K030744), which has been cleared by FDA for use in patients with tumor, trauma or fractures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Mr. Dean E. Ciporkin
Director, Regulatory Affairs and Quality Assurance
Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K032700
Trade Name: Blackstone™ Surgical Titanium Mesh System Angled End Rings
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP (Vertebral Body Replacement Device)
Dated: August 25, 2003
Received: September 11, 2003

Dear Mr. Ciporkin:

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.

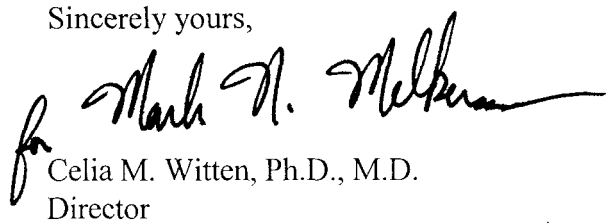
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/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: K032700

Device Name: ***Blackstone™ Surgical Titanium Mesh System Angled End Rings***

Indications for Use:

The Blackstone Medical Surgical Titanium Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Surgical Titanium mesh is also indicated for treating fractures of the thoracic and lumbar spine.

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Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhous

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

510(k) Number K032700

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)