

AUG 17 2004

510(K) SUMMARY

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**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™ PEEK Vertebral Body Replacement System  
Lordotic Lateral Spacers

**Common Name:** Spinal Vertebral Body Replacement Device

**Device Product Code  
& Classification:** MQP- 888.3060 – Spinal Vertebral Body Replacement Device

**Substantially  
Equivalent Devices:** Blackstone PEEK Vertebral Body Replacement System  
(K033702)

**Device Description:**

Blackstone Medical, Inc. PEEK Vertebral Body Replacement (VBR) System is comprised of a variety of components fabricated and manufactured from Polyetheretherketone (PEEK Optima LT) as described by ASTM F-2026. This material is utilized due to its radiolucent properties, which aid the surgeon in determining if fusion in the operative site has occurred. Titanium markers are inserted into components to give surgeons a visual aid in determining the location of the implant both inter and postoperatively. The superior and inferior surfaces of the construct have a pattern of ripples to provide increased stability and help prevent lateral movement of the device.

The Lordotic Lateral Spacers restore the natural curvature of the spine.

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**Intended Use / Indications for Use:**

The Blackstone Medical PEEK Vertebral Body Replacement 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 PEEK VBR System is also indicated for treating fractures of the thoracic and lumbar spine. It is recommended that bone graft material be packed inside the system prior to implantation. The PEEK VBR System is intended to be used with supplemental internal fixation. Specifically, the supplemental internal fixation system that may be used with the PEEK VBR System is the Blackstone Medical Spinal Fixation System.

**Basis of Substantial Equivalence:**

The Blackstone™ PEEK Vertebral Body Replacement System Lordotic Lateral Spacers are substantially equivalent to the Blackstone™ PEEK Vertebral Body Replacement System (K033702), which has received market clearance by the FDA.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 17 2004

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

Re: K041939

Trade/Device Name: Blackstone™ PEEK VBR System Lordotic Lateral Spacers  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: MQP  
Dated: July 16, 2004  
Received: July 19, 2004

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.

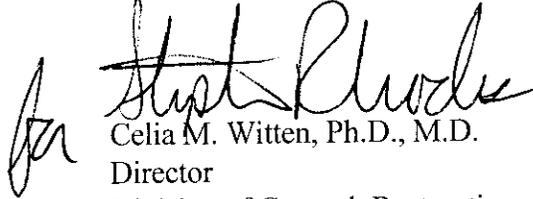
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Dean E. Ciporkin

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) 594-4692. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". To the left of the signature is a small, stylized handwritten mark that looks like "for".

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

510(k) Number (if known): K041939

Device Name: Blackstone PEEK VBR System Lordotic Lateral Spacers

### Indications for Use:

The Blackstone VBR device 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 Blackstone VBR device is also indicated for treating fractures of the thoracic and lumbar spine.

The Blackstone VBR device 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. Additionally, the VBR device is intended to be used with bone graft.

The Blackstone VBR device is intended for use with supplemental internal fixation. The supplemental internal fixation system that may be used is the Blackstone Spinal Fixation System.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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