K043548
1 of 2

JUN 14 2005

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™ Unity™ Anterior Lumbar Plate Fixation System
Common Name:	Spinal Intervertebral Body Fixation Orthosis
Device Product Code & Classification:	**KWQ**–888.3060 – Appliance, Fixation, Spinal Intervertebral Body
Substantially Equivalent Devices:	Medtronic Sofamor Danek Pyramid™ Anterior Plate Fixation System (K013665)

Device Description:
The Blackstone Unity™ Anterior Lumbar Plate Fixation System is comprised of non-sterile, single use, titanium alloy components. The system is designed for use as a supplemental fixation device for the lumbosacral level, below the bifurcation of the vascular structures. The components are offered in a variety of sizes in order to accommodate specific needs during surgery.

Intended Use / Indications for Use:
The Blackstone Unity™ Anterior Lumbar Plate Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures.

When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

a) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies)
b) Pseudoarthrosis
c) Spondylolysis
d) Spondylolisthesis
e) Fracture
f) Neoplastic disease
g) Unsuccessful previous fusion surgery
h) Lordotic deformities of the spine
i) Idiopathic thoracolumbar or lumbar scoliosis
j) Deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele
k) Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity

Basis of Substantial Equivalence:
The Blackstone Unity™ Anterior Lumbar Plate Fixation System is substantially equivalent to the Medtronic Sofamor Danek Pyramid™ Anterior Plate Fixation System (K013665), which has been cleared by FDA for use as a fixation device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2005

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

Re: K043548
Trade/Device Name: UNITY Anterior Lumbar Plate System
Regulation Number: 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 25, 2005
Received: May 26, 2005

Dear Mr. Ciporkin:

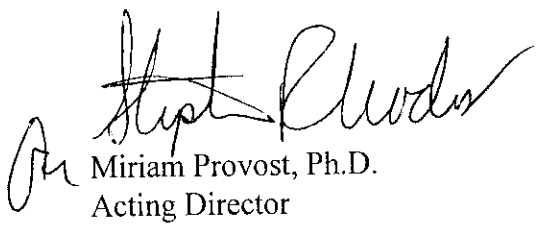
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Miriam Provost, Ph.D.
Acting 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): K043548

Device Name: Blackstone™ Unity™ Anterior Lumbar Plate Fixation System

Indications for Use:

The Blackstone Unity™ Anterior Lumbar Plate Fixation System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures.

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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

510(k) Number K043548