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K043338

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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™ Laminoplasty Fixation System
Common Name:	Interlaminal Fixation Appliance
Device Product Code & Classification:	**NQW**– 888.3050 –Orthosis, Spine, Plate, Laminoplasty, Metal
Substantially Equivalent Devices:	Synthes Arch™ Fixation System (K032534)

Device Description:

The Blackstone Laminoplasty Fixation System is a device comprised of non-sterile, single use, titanium and titanium alloy components. The specially shaped plates, made of commercially pure (CP) titanium, are designed to fit the anatomy of the dorsally elevated lamina. The plates have screw holes on both ends, which allow for attachment to the vertebral body, and a screw hole in the center for attachment to the allograft.

The screws, made of titanium alloy (6AL-4V ELI, per ASTM F-136), are available in variety of lengths and diameters in order to meet individual anatomical requirements.

Intended Use / Indications for Use:

The Blackstone Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent expulsion of the allograft, or impingement of the spinal cord.

Basis of Substantial Equivalence:

The Blackstone Laminoplasty Fixation System is substantially equivalent to the Synthes Arch™ Fixation System (K032534), which has been cleared by FDA for use as a laminoplasty fixation device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

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

Re: K043338
Trade/Device Name: Blackstone ™ Laminoplasty Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: NQW
Dated: January 28, 2005
Received: February 1, 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.

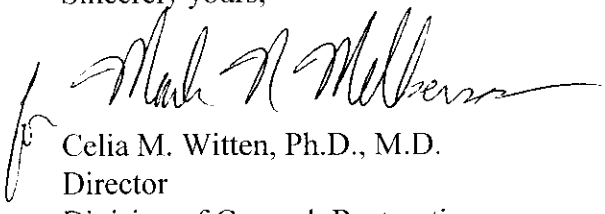
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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,



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): K043339

Device Name: Blackstone™ Laminoplasty Fixation System

Indications for Use:

The Blackstone Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Laminoplasty Fixation System holds or buttresses the allograft in place in order to prevent expulsion of the allograft, or impingement of the spinal cord.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

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

510(k) Number K043338