K042100

SEP 20 2004

K 042100

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™ Ascent POCT System
5.5mm/3.0mm Single Axial Connector

Common Name: Rod and Screw Spinal Instrumentation

Device Product Code & Classification:
MNI - 888.3070 – Pedicle Screw Spinal System
KWP - 888.3050 - Spinal Interlaminal Fixation Orthosis

Substantially Equivalent Devices:

Blackstone™ Ascent POCT System (K030197)

Device Description:

The Blackstone™ Ascent POCT System is a titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The Blackstone™ Ascent POCT System consists of an assortment of rods, set-screws, cross connectors, multi-axial screws, plates, bone screws and Songer Cables.

The 5.5mm/3.0mm Single Axial Connector addition will function as a rod connector. There are clinical applications in which a surgeon will need to have the inter-operative ability to connect rods of different diameter when extending a construct.

1.5 Intended Use / Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Blackstone™ Ascent POCT System is indicated for:

a) degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
b) spondylolisthesis
c) spinal stenosis
d) fracture/dislocation
e) atlanto/axial fracture with instability
f) occipitocervical dislocation
g) revision of previous cervical spine surgery
h) tumors

The occipital bone screws are limited to occipital fixation only.

The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The Songer Cable System to be used with the Blackstone™ POCT System allows for wire/cable attachment to the posterior cervical spine.

The Blackstone Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial Connector.

BASIS OF SUBSTANTIAL EQUIVALENCE:
By its very nature, the Blackstone™ 5.5mm/3.0mm Single Axial Connector is substantially equivalent to the Blackstone™ Ascent POCT System (K030197), which has been cleared by FDA for posterior fixation applications to the occipito-cervical-thoracic junction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2004

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

Re: K042100
Trade/Device Name: Blackstone™ Ascent POCT System 5.5mm/3.0mm Axial Connector
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, KWP
Dated: August 2, 2004
Received: August 4, 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.

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,

Miriam C. Provost

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): _____

Device Name: Blackstone™ Ascent POCT System 5.5mm/3.0mm Single Axial Connector

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Blackstone™ Ascent POCT System is indicated for:

a) degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
b) spondylolisthesis
c) spinal stenosis
d) fracture/dislocation
e) atlanto/axial fracture with instability
f) occipitocervical dislocation
g) revision of previous cervical spine surgery
h) tumors

The occipital bone screws are limited to occipital fixation only.

The use of the multi-axial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The Songer Cable System to be used with the Blackstone™ POCT System allows for wire/cable attachment to the posterior cervical spine.

The Blackstone Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial Connector

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)

Miriam C. Provost

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

510(k) Number K042100