K080394

510(K) SUMMARY

MAR 13 2008

Name of Firm: Blackstone Medical, Inc.
1211 Hamburg Turnpike
Wayne, NJ 07470

510(k) Contact: Whitney Törning, Senior Director of Regulatory Affairs & Quality Assurance

Submitter: Martin Sprunck, Regulatory Affairs Manager

Trade Name: Blackstone™ Ascent® Posterior Occipital Cervico-Thoracic (POCT) System

Common Name: Rod and screw spinal instrumentation

Device Classification: Class II

Classification Product Code: **KWP** – 888.3050 – Spinal Interlaminal Fixation Orthosis

Substantially Equivalent Devices:

Blackstone™ Posterior Cervical System (K030197 SE 6-12-03)
Blackstone™ Ascent POCT System Lateral Offset Adaptors (K040034 SE 2-11-04)
Blackstone™ Ascent POCT System Hooks (K033980 SE 3-3-04)
Blackstone™ Ascent POCT System 5.5mm/3.0mm Single Axial Connector (K042100 SE 9-20-04)
Blackstone™ Ascent POCT System Parallel Rod Connectors (K073654 SE 1-24-08)

Device Description:

Description: The Blackstone Ascent POCT System is a temporary, 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 Ascent POCT System consists of an assortment of rods, setscrews, cross connectors, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and Songer Cables.

Levels of Use: When used in the occipito-cervico-thoracic spine, the Blackstone Posterior Cervical System may be used from the occiput to T3.

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

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) for the treatment of thoracic conditions only. They are not intended to be placed in the cervical spine. The lateral offset adapter is indicated for use in the upper thoracic spine (T1-T3). The hooks are intended to be placed from C1 to T3. The Songer Cable (titanium) System to be used with the Blackstone Ascent POCT System allows for wire/cable attachment to the posterior cervical spine.

The Blackstone Ascent POCT System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial or Parallel Connector.

Basis of Substantial Equivalence:

The modified Blackstone™ Ascent Occipital Plate and Occipital-Transition Rod are substantially equivalent to the identified predicate systems, which have been cleared by FDA for the purpose of building a spinal implant construct in the occipito-cervico-thoracic spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

Blackstone Medical, Inc.
% Ms. Whitney Törning
Senior Director of Regulatory Affairs and Quality Assurance
1211 Hamburg Turnpike, Suite 300
Wayne, NJ 07470

Re: K080394
Trade/Device Name: Ascent® Posterior Occipital Cervico-Thoracic (POCT) System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: February 11, 2008
Received: February 13, 2008

Dear Ms. Törning:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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 Posterior Occipital Cervical Thoracic System (POCT) System

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 (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
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c) fracture/dislocation;
d) spinal stenosis;
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The Blackstone Ascent Posterior Occipital Cervical Thoracic System can also be linked to the Blackstone Spinal Fixation System using the Blackstone Ascent Axial or Parallel Rod 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)

Neil R Ogden for MKM

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

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