

JUN 17 1998

K974885

Blackstone Medical Inc. Anterior Cervical Plate System  
510(k) Summary

Company: Blackstone Medical Inc.  
90 Brookdale Drive  
Springfield, MA 01104  
Phone: 413 731-8711

Tradename: Blackstone Medical Inc. Anterior Cervical Plate System

Classification: Spinal Intervertebral Body Fixation Orthosis

Description: The principal components of the Blackstone Medical Inc. Anterior Cervical Plate System are plates, screws, and locking plate made from titanium 6Al-4V Eli alloy, as per ASTM F-136. The instrument set includes

6 Degree/15 Degree Plate Holder and Guide  
6 Degree/0 Degree Plate Holder and Guide  
Freehand Guide  
Drill with Adjustable Stop  
Bone Tap with Adjustable Stop  
Bone Screw Driver  
Lock Plate Screw Driver  
Plate Bender  
Tack and Tack Holder

After determining the appropriate plate length, the plate is positioned on the anterior surface of the cervical spine. The cannula is seated into the plate at the correct cranial /caudal and convergent angle. Once the drill bit has been placed in the cannula and drilled, the tap is inserted into the cannula, the vertebral bodies are tapped and the screws are inserted. The screws are then tightened to ensure that they are seated below the surface of the plate. The cannula is removed. The lock plate is positioned over the bone screws and secured with lock plate screw driver.

Material: The components of the Blackstone Medical Inc. Anterior Cervical Plate System are manufactured from titanium 6Al-4V Eli alloy, as described by ASTM F-136.

Indications: The Blackstone Medical Inc. Anterior Cervical Plate System indicated for use in stabilizing the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

a) degenerative disc disease (ddd)\*

\*Back pain of discogenic origin with degeneration of the disc as confirmed by history and radiographic studies.

b) spondylothesis

- c) fracture
- d) spinal stenosis
- e) deformities (i.e., scoliosis, kyphosis, lordosis)
- f) tumor
- g) pseudoarthrosis
- h) revision of previous failed fusion surgery.

**Performance** The Blackstone Cervical Plate was compared to a Synthes Cervical Plate per FEA analysis to determine the difference in stiffness and stress. The plates were similar in length. The Blackstone Plate was 288% stiffer than the Synthes Plate and the maximum stress associated with the Blackstone Plate was 41% less than the Synthes Plate.

**Substantial  
Equivalence:** The Blackstone Medical Inc. Anterior Cervical Plate System is equivalent to the CODMAN Anterior Cervical Plate System, SYNTHES Cervical Locking Plate System and SOFAMOR DANEK ORION Anterior Cervical Plate System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Matthew Lyons  
President  
Blackstone Medical, Inc.  
90 Brookdale Drive  
Springfield, Massachusetts 01104

Re: K974885  
Anterior Cervical Plate System  
Regulatory Class: II  
Product Code: KWQ  
Dated: April 9, 1998  
Received: April 10, 1998

Dear Mr. Lyons:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the package insert must include the following statement,

**"WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine."

2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and
3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

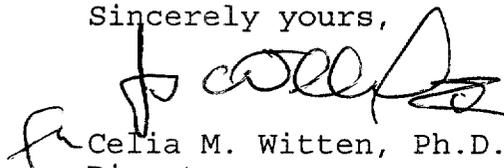
FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or other manufacturers', may also be required.

Page 3 - Mr. Matthew Lyons

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510 (k) Number (if known): K974885

Device Name: ANTERIOR CERVICAL PLATE SYSTEM

**Intended Use/Indications:**

The BLACKSTONE MEDICAL, INC. Anterior Cervical Plate System is to be used for anterior screw fixation of the cervical spine (C2--C7). The indications are as follows:

Indications:

- Degenerative Disc Disease (ddd)\*
- \*Back pain of discogenic origin with degeneration of the disc as confirmed by history and radiographic studies.
- Spondylolisthesis
- Fracture
- Spinal Stenosis
- Deformities (i.e., scoliosis, kyphosis, lordosis)
- Tumor
- Pseudoarthrosis
- Revision of previous failed fusion surgery

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

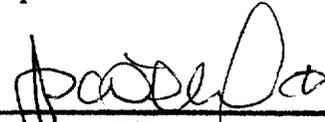
\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

Or

Over-the-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)



\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number \_\_\_\_\_

K974885