

OCT 8 1999

K993025

INTRODUCTORY INFORMATION

Sponsor: Biomet, Inc.
Manufacturer: Biomet Manufacturing, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Establishment Registration: 1825034

Contact Person: Fred McClure
(219) 372-1568

Distributor: Arthrotek
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Devices are manufactured and packaged in the Warsaw, Indiana facility which is also the headquarters of Biomet, Inc.

The device will be distributed by Arthrotek, a wholly owned subsidiary of Biomet, Inc.

Proprietary Name: Bone Mulch Screw System

Common or Usual Name: ACL Graft Femoral Fixation Screw

Classification Name: Screw, Fixation, Bone

Device Classification: 21 CFR 888.3040

Device Product Code: 87HWC

Performance Standards/Guidance Documents: No performance standards have been developed for this type of device

Previous FDA Status: Devices from this system were previously cleared in 510(k) K941941 and K991298.

Device Description: The predicate Bone Mulch Screw System consists of three different Bone Mulch Screws made of Titanium alloy Ti-6Al-4V per ASTM F-136 which are available in different lengths as well as cannulated and non-cannulated configurations. The Cannulated Bone Mulch Screw is comprised of two components, the cannulated screw and either a titanium screw plug or an

000003

UHMWPE plug. The cannulated screw portion has a blunt nose, available in a standard or +5mm length, which resides across the femoral bone tunnel. The tendon graft is wrapped over this portion of the cannulated screw and never comes in contact with the threads of the cannulated screw. The larger threaded, portion of the cannulated screw resides in the femoral bone adjacent to the tunnel and acts as a passageway for bone graft. The opening in the cannulated screw just prior to the blunt nose allows for passage of bone graft to lie adjacent to the tendon graft to aid in graft incorporation. The bone graft material is pushed into the bone tunnel by a graft insertion rod. The bone graft material is secured at the reconstruction site by inserting either the titanium screw plug or the UHMWPE plug into the hollow end of the screw. The UHMWPE plug is designed to allow the surgeon to insert it with the graft insertion rod. The non-cannulated Bone Mulch Screw is identical to the cannulated Bone Mulch Screw in design and function but is solid and does not require bone graft to be packed inside it.

The modified design continues the cannulation into the nose allowing the screw to be passed over a wire . The added length to the tip will cause the screw to go deeper into the medial wall of the graft tunnel thereby preventing the most likely failure mode of the screw – the tip being pried downward into the tunnel in a cantilever manner.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Fred McClure
Regulatory Specialist
Biomet, Inc.
Airport Industrial Park
P. O. Box 587
Warsaw, Indiana 46581-0587

Re: K993025
Trade Name: Bone Mulch Screw System
Regulatory Class: II
Product Code: HWC
Dated: August 19, 1999
Received: September 09, 1999

Dear Mr. McClure:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to 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). 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.

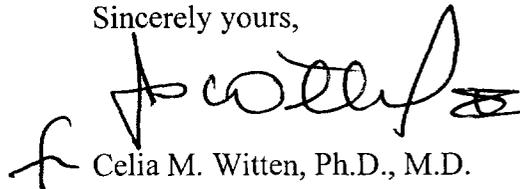
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Fred McClure

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

Enclosures

510 (k) Number (if known) : _____

Device Name: Bone Mulch Screw System

Indications For Use: The Bone Mulch Screw System is indicated for use in anterior cruciate ligament (ACL) reconstruction using semigracilis/semitendinosus or fascia lata (hamstring tendons) graft. It is intended for use in fixing the graft within the femoral graft tunnel.

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

Prescription Use _____

(Per 21 CFR 801.109)

X

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

[Handwritten Signature]

K993025
600008