

MAY 14 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

K991298

Sponsor: Biomet, Inc.
Airport Industrial Park
Warsaw, Indiana 46580

Device: Bone Mulch Screw

Classification Name: Screw, Fixation, Bone

Intended 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.

Device Description: The Bone Mulch Screw System consists of three different Bone Mulch Screws made of Titanium alloy, available in different lengths as well as cannulated and non-cannulated configurations, a titanium screw plug and an UHMWPE plug. The blunt nose of the screw transverses the femoral tunnel allowing for femoral fixation of the ACL graft. With the graft wrapped over the blunt nose of the screw, the larger portion of the cannulated screw is packed with bone graft material. The bone graft material is pushed into the tunnel by a graft insertion rod and secured in place with either the titanium screw plug or the UHMWPE plug. The non-cannulated screw is used in the same manner but does not require the addition of bone graft to fill the screw.

The Bone Mulch Screw and titanium screw plug is made of titanium alloy Ti-6Al-4V per ASTM F136 and the poly plug is made of UHMWPE. These materials have been successfully used as implantable materials for the past several decades. The biocompatibility and wear properties have been established by many years of usage in medical devices.

Mechanical testing of this device demonstrated more than adequate strength for this ACL reconstruction indication. In summary, the device is made of biocompatible materials and is able to withstand loads greater than those expected in an intact ACL.

Possible Adverse Effects:

- 1) Inadequate healing which may lead to breakage of the implant.
- 2) Fracture of the implant due to excessive activity.
- 3) Loosening and/or migration of the implant.
- 4) Metal sensitivity, or allergic reaction to a foreign body.
- 5) Pain, discomfort or abnormal sensations due to the presence of the device.
- 6) Nerve damage due to surgical trauma.
- 7) Necrosis of bone or bone resorption.
- 8) Necrosis of tissue or inadequate healing.

Substantial Equivalence: In function and overall design the Prosthesis is equivalent to

000113



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 14 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: K991298
Trade Name: Bone Mulch Screw System
Regulatory Class: II
Product Code: HWC
Dated: April 13, 1999
Received: April 15, 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 enclosure) 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.

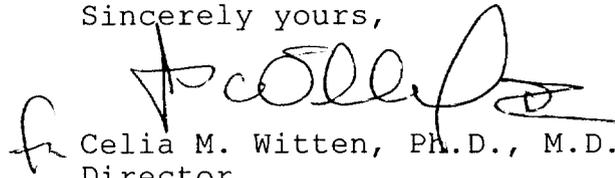
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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) 594-4659. 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) : K991298

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.

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of **General Restorative Devices** K991298
510(k) Number _____

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