

NOV 16 1999

SUMMARY OF SAFETY AND EFFECTIVENESS**Sponsor:** Biomet, Inc.**Manufacturer:** Biomet Manufacturing, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587**Proprietary Name:** Modified BMP™ Trochanteric Plates**Common or Usual Name:** Single/Multiple Component Metallic Bone Fixation Appliances**Classification Name:** Bone, Fixation, Plate 888.3030**Device Classification:** Class II**Device Description:** The Modified BMP™ Trochanteric Plates consist of crimps and trochanteric plates. The crimps are made of either 316LVM stainless steel or Co-Cr-Mo. The CoCr crimps are to be used in conjunction with CoCr wire and stainless steel crimps are to be used in conjunction with stainless steel wire.

The trochanteric plates are made of CoCrMo and are available in two different lengths. The shorter plate is available in both right and left configurations while the longer plate will be straight and have a different contour in the trochanter region than the shorter plates.

Indications For Use:

Lateral Trochanteric Plates: extended trochanteric osteotomies, trochanteric fractures, trochanteric osteotomies.

Potential Risks:

1. Nonunion or delayed union which may lead to breakage of implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Limb shortening due to compression of the fracture or bone resorption.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensation due to the presence of the device.
8. Nerve damage due to surgical trauma.
9. Necrosis of bone.
10. Postoperative bone fracture and pain.
11. Inadequate healing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993510
Trade Name: Modified BMP™ Trochanteric Plates
Regulatory Class: II
Product Code: HRS
Dated: October 15, 1999
Received: October 18, 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.

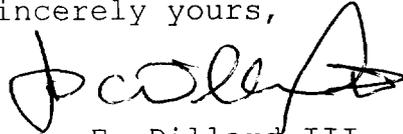
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

A handwritten signature in black ink, appearing to read "J. Dillard III", written over a horizontal line.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K 993510

Device Name: Modified BMP™ Trochanteric Plates

Indications For Use:

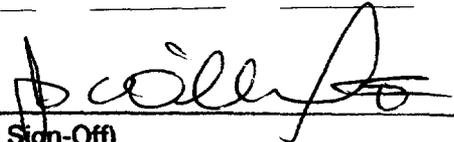
Lateral Trochanteric Plates: extended trochanteric osteotomies,
trochanteric fractures, trochanteric osteotomies.

(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 K993510