NOV - 3 2000

K003294

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Tracy J. Bickel
(219) 372-1761

Device(s): Biomet® Lateral Troch Plate

Classification Name: Bone, Fixation, Cerclage 888.3010
Plate, Fixation, Bone 888.3030

Device Classification: Class II

Device Product Code: 87 JDQ
87 HRS

Intended Use:

- Extended trochanteric osteotomies
- Trochanteric fractures

Device Description:
The lateral troch plate consists of two regions, a plate region, and a hook or troch region. The hook region is curved to match the contour of the femur in the area of the greater trochanter. There are two screw holes in the hook area that will accommodate 6.5mm cancellous screws. The plate region is straight and has a combination of 4.5mm cortical screw holes and integrated cable crimp sleeves. The plates are composed of 316LVM Stainless Steel conforming to ASTM F138.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disease	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

Predicate Device(s):
Biomet's BMP™ Cable System- K982545

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Ms. Tracy J. Bickel
Biomet Inc.
P.O.Box 587
Warsaw, Indiana 46581

Re: K003294
Trade Name: Biomet Lateral Troch Plate
Regulatory Class: II
Product Code: JDW, HRS
Dated: October 19, 2000
Received: October 20, 2000

Dear Ms. Bickel:

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 control provisions of the Act. The general control 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.

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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

Enclosure

510(k) Number (if known): K003294
Device Name: **Biomet® Lateral Troch Plate**
Indications for Use:

- Extended trochanteric osteotomies
- Trochanteric fractures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003294

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