JAN 19 1999

K984028

SUMMARY OF SAFETY AND EFFECTIVENESS

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

CONTACT PERSON: Tracy J. Bickel

DEVICE: The New Bio-Moore Endo Heads

CLASSIFICATION NAME: Prosthesis hip, hemi, metal ball

INTENDED USE: The New Bio-Moore Endo Heads is indicated for use in:

a.) non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
b.) rheumatoid arthritis
c.) revisions procedures where other devices or treatments have failed
d.) correction of functional deformities
e.) Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement.

The Bio-Moore Endo Heads are intended for impaction on either a press-fit or cemented femoral component and are for single use implantation.

DEVICE DESCRIPTION: The New Bio-Moore Endo Heads are used as a hemi device and only replaces the head and not the acetubulum. The purpose is to preserve as much bone as possible. The heads allows for the use of taper inserts to vary the lengths of the neck which allows the surgeon greater flexibility in the OR. The taper inserts are assembled during surgery to insure an accurate fit.

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:

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

SUBSTANTIAL EQUIVALNCE: The Bio-Moore Endo Heads are similar to all other devices on the market in terms of intended use and design.

Predicate devices include:

Unitrax V40 Modular Adaptor (Howmedica, Rutherford, NJ) 510(K) #K954077
Osteo Austin Moore Endoprostheis System (Osteonics , Allendale, NJ) 510(K) #K974807
Prime Modular Endo Head (Orthopaedic Innovations, Minneapolis, MN) 510(K) #K962646
Opteon Unipolar Endoprosthesis (Exactech, Gainesville, FL) 510(K) #K960538
Ultima Unipolar head and Adapter Sleeves (Johnson & Johnson, Raynham, MA) 510(K) #K965156
Austin Moore Endoprosthesis (Biomet, Warsaw, IN) 510(K) #K845025

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 1999

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K984028
Trade Name: New Bio-Moore Endo Head
Regulatory Class: II
Product Code: KWL
Dated: November 2, 1998
Received: November 12, 1998

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 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.

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,

for 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: K984028
DEVICE NAME: The New Bio-Moore Endo Head

The indications for use are:

a.) non-inflammatory degenerative joint disease, including avascular necrosis and osteoarthritis.
b.) rheumatoid arthritis
c.) correction of functional deformities
d.) revision procedures where other devices or treatments have failed
e.) treatment of non-unions, femoral neck trochanteric fractures of the proximal femur with neck involvement

The New Bio-Moore Endo Heads are intended for impaction on either a press-fit or cemented femoral component and are for single use implants.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K98402