2/18/99

K984296

SUMMARY OF SAFETY AND EFFECTIVENESS

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

CONTACT PERSON: Dalene Hufziger Binkley

DEVICE NAME: Lateralized Integral Hip Component

CLASSIFICATION NAME: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. §888.3350

DEVICE PRODUCT CODE: 87LPH

CLASSIFICATION TYPE: II

INTENDED USE: The indications for Lateralized Integral Hip Component are the same as with any other hip replacement, namely:

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

The Lateralized Integral Hip Component is intended for press-fit application and single use implantation.

DEVICE DESCRIPTION: The Lateralized Integral Hip Component is an evolution of Biomet's successful BiMetric family. The lateralizion is achieved by moving the trunion/taper 6-mm medially, thereby moving the axis of rotation 6-mm lateral. The horizontal offset of the femoral neck addresses the need to increase joint stability by tensioning the soft tissue. The same design is employed on the Lateralized Taperloc, another of Biomet's stems.

The proximal geometry of the Integral femoral component is designed to promote distal filling of the metaphysis. A porous coated duckbill collar is incorporated to provide stability and stress transfer. This helps to provide rotational stability and facilitates potential ingrowth and load transfer.

The proximal to distal taper of the femoral stem parallels the shape of the femur canal, allowing a gradual decrease in the stresses transferred to the bone from proximal to distal.

The 3-degree compound proximal to distal taper helps the device to achieve exceptional fit. The stems are proportionally sized and shaped 9- mm to 19-mm diameters in 1-mm increments, and from 125 to 175 mm in length in 5 increments. The straight stem design of the primary component eliminates the need for a left or right configurations.

The femoral component utilizes a modular head, which is taper-fit on to the stem at the time of surgery. The modular head is manufactured from wrought titanium or cobalt-chromium-molybdenum conforming to ASTM F-620 and F-1537 respectively.

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 the joint	Excessive wear
Tissue growth failure	Infection
Delayed wound healing	Dislocation
Metal sensitivity	Breakdown of the porous surface

SUBSTANTIAL EQUIVALENCE: The Lateralized Integral femoral component is similar to most femoral component on the market today in terms of overall intended function and design. Direct comparison was made with the following predicates:

Biomet Integral Primary Porous	K921225
Biomet Lateralized Taperloc Hip System	K921301

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Ms. Dalene Hufziger Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K984296
Trade Name: Lateralized Integral Hip Component
Regulatory Class: II
Product Codes: LPH and JDI
Dated: November 23, 1998
Received: December 1, 1998

Dear Ms. Binkley:

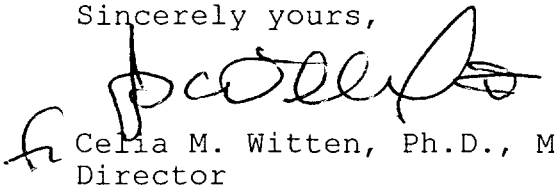
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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: K984296

DEVICE NAME: Lateralized Integral Hip Stem

The indications for use are:

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

The Lateralized Integral Hip Stem is intended for press-fit application and is for single use implantation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

or Over the Counter-Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984296