2/12/99

K984408

BIOMET INC®

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR: Biomet, Inc

DEVICE: 130° Integral Modified Femoral Component

CLASSIFICATION NAME:
- Prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented (888.3558)
- Prosthesis, hip, semi-constrained, metal/polymer, cemented (888.3350)

INTENDED USE: The 130° Modified Integral Femoral Components are intended for use in cases with a diagnosis of:

a) non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
b) rheumatoid arthritis
c) non-union, femoral neck, and trochanteric fractures of the proximal femur with head involvement.
d) correction of functional deformities
e) revisions of previously failed surgeries and treatments

The 130° Modified Integral Femoral Component is intended for press-fit or cemented application. The device is a single use implant.

DEVICE DESCRIPTION: The device is composed of a forged titanium stem, which is designed to articulate with any commercially available acetabular component. The device is a modification of Biomet's standard Integral femoral component in that the trunion has been moved inferiorly, medially and rotated 10°. This results in a 130° neck angle as opposed to the standard 140° neck angle. Advantages of a reduced neck angle include potential increased joint stablity by improving soft tissue tension. The remainder of the stem is identical to that of the Biomet's standard Integral femoral stems. The device features a duck-bill collar to provide implant stablity. The modified device has a reduced proximal profile. The device utilizes a modular head that is taper-fit on to the stem at the time of surgery.

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

SUBSTANTIAL EQUIVALENCE: The 130° Degree Integral Modified Femoral Component is substantially equivalent to most femoral devices on the market in overall design and intended function. Predicate devices include:

Integral Total Hip System (Biomet, Inc.)	K921225
Omni-Fit (Osteonics)	K940715(?)
Natural Hip (Intermedics (Sulzer) Orthopaedics)	K920955

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K984408
Trade Name: 130° Modified Integral Femoral Components
Regulatory Class: II
Product Codes: LPH and JDI
Dated: December 7, 1998
Received: December 9, 1998

Dear Ms. Beres:

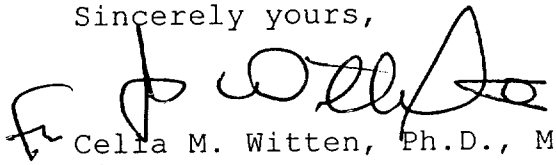
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K984408

Device Name: 130° Modified Integral Femoral Components

Indications For Use:

a) non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
b) rheumatoid arthritis
c) non-union, femoral neck, and trochanteric fractures of the proximal femur with head involvement.
d) correction of functional deformities
e) revisions of previously failed surgeries and treatments

The 130° Modified Integral Femoral Component is intended for press-fit or cemented application. The device is a single use implant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984408

Prescription Use N/A
(Per 21 CFR 801.109)

OR

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