K991990

SEP 10 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

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

CONTACT PERSON: Michelle L. McKinley

DEVICE NAME: Tri-Polar System

CLASSIFICATION NAME: Prosthesis, hip, semi-constrained metal/polymer, cemented
Prosthesis, hip, semi-constrained metal/polymer, uncemented

INTENDED USE:

The Tri-Polar System is indicated for use in patients requiring total reconstruction of the hip joint due to the following:

a.) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
b.) Rheumatoid arthritis.
c.) Correction of functional deformity.
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previously failed total hip arthroplasty due to recurrent dislocations.

The Tri-Polar System is intended for cemented or press-fit application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

DEVICE DESCRIPTION:

The Tri-Polar prosthesis consists of a Bi-Polar femoral head, which articulates with a mating acetabular liner that fits into any standard line acetabular component. Once the Bi-Polar femoral head is used with an acetabular component the device becomes the Tri-Polar.

The Tri-Polar System consists of an all polyethylene or metal backed acetabular cup with a polyethylene liner designed to fit on a Bi-Polar head. The Bi-Polar femoral head component

contains a modular head, which is attached to the femoral stem component. In other words, the Tri-Polar system adds an acetabular bearing component to a Bi-Polar hip replacement.

The Tri-Polar liners fit into any currently approved Biomet RingLoc® acetabular shells. The liner is retained in the shell by means of Biomet's standard RingLoc® mechanism. (A current listing of shells is found in Exhibit I). The liner and shell are properly aligned with one another and then locked into position with a metal ring (RingLoc®). The metallic shell has six to eight scalloped semi-circles, which mate with analogous semi-circular cutouts on the liner for prevention of rotation.

Biomet's all polyethylene acetabular cup has two outer concentric rings to facilitate cement interdigitation and an embedded wire for x-ray visualization. The all polyethylene has two outer concentric rings to facilitate cement interdigitation and an embedded wire for x-ray visualization. The all polyethylene acetabular component is intended to be cemented in the aceatabulum or used with a Biomet recovery cage.

The Bi-Polar femoral head consists of a larger outer shell with a polyethylene insert, which contains within it a modular head. The modular head is captured by the polyethylene insert, which is captured by means of a RingLoc® mechanism similar to that previously described above. The 22mm Bi-Polar component can be used with either size 24 or 25 Tri-Polar liners or the 54, or 57 all polyethylene cup. While the 28mm Bi-Polar component can be used with either size 26, 27, or 28 Tri-Polar liners or the 63, 66, or 69 all polyethylene cup. A polyethylene thickness of 4.0mm is the general standard for a hip prosthesis. The Tri-Polar system utilizes a minimum thickness of 4.8mm, which is greater than the general standard.

The Tri-Polar System does not incorporate any new technology that has not previously been available. The device simply combines this technology.

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 Tri-Polar Acetabular System is similar to previously marketed devices. The device is similar to a traditional hip device consisting of a femoral stem, modular head, and metal backed polyethylene component, with the addition of a Bi-Polar bearing surface between the modular head and acetabular bearing surface. Direct comparison was made with the following predicates:

THARIES Surface Replacement System
Indiana Conservative Hip
Mallory Head Total Hip

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K991990
Trade Name: TriPolar System
Regulatory Class: II
Product Code: KWY and LPH
Dated: June 4, 1999
Received: June 14, 1999

Dear Ms. McKinley:

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: K991990
Device Name: Tri-Polar System

The indications for use are:

a.) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previously failed total hip arthroplasty due to recurrent dislocation.

The Tri-Polar System is intended for cemented or press-fit application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

(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 CFR 801.109)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991990