K994184

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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 NAME: PLR Splined Revision Stem

CLASSIFICATION NAME: Prosthesis, hip, semi-constrained metal/ceramic/polymer, cemented or non-porous uncemented (21 CFR 888.3350)

INTENDED USE:

The PLR Splined Revision Stem 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 PLR Splined Revision Stem is intended for press-fit application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints.

DEVICE DESCRIPTION:

The PLR Splined Revision Stem is a one-piece, press-fit revision stem machined from wrought Titanium (Ti-6Al-4V). The region above the resection level has a machine finish and the remainder of the stem is a grit blast finished.

The distal portion of the stem has splines. The neck-shaft angle is 135 degrees. The lateral offset for a standard 28mm head is 42mm on all sizes. The stem is 270 mm in length measured from the medial resection level to the distal end. Sizes range from 14mm to 24mm in 1mm increments.

The stem has the standard Biomet, Inc. Type I taper to fit all sizes and types of modular femoral heads. Neck flats are present for stem removal if necessary. The

proximal region of the stem has a lateral flare with three holes to use with CoCr cables/wires for attachment of the greater trochanter.

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:

Direct comparison was made with the following predicates:

1) Wagner Revion Stem: K960588
   Manufactured by Intermedics (Austin, TX)

2) Wagner Revisional Femoral Hip Prosthesis: K871347
   Manufactured by Protek (Indianapolis, IN)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2000

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

Re: K994184
Trade Name: PLR Splined Revision Stem
Regulatory Class: II
Product Code: LZO & JDI
Dated: December 7, 1999
Received: December 10, 1999

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) 594-4595. 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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994184
Device Name: PLR Splined Revision Stem
Indications for Use:

The PLR Splined Revision Stems 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 PLR Splined Revision Stem is intended for press-fit application for general use in skeletally mature individuals undergoing surgery for rehabilitating hip joints. This 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 K994184

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)