2/18/99

K990032

SUMMARY OF SAFETY AND EFFECTIVENESS

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

CONTACT PERSON: Dalene Hufziger Binkley

PROPRIETARY NAME: Modular Protrusio Cup

DEVICE NAME: Hip joint metal/polymer semi-constrained cemented prosthesis 888.3350.

INTENDED USE: The indications for the Modular Protrusio Cup are as follows:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of nonunion, femoral neck fractures, and throchanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
5) Revision of failed joint construction or treatment

DEVICE DESCRIPTION: The Modular Protrusio Cup is a hemispherial metallic cup with a hook, flange, or blade extending from it. The ilium flange and hook are fabricated from commercially pure (CP) titanium. The cup and blade are made from titanium alloy. The malleable commercially pure (CP) titanium flange and hook can be shaped by the surgeon intraoperatively to fit the shape of the patient's anatomy. The surface of the hook and blade has a grit blasted (roughened) finish for potential enhanced fixation to the bone. The cup will have plasma spray porous coating to enhance potential fixation to any host bone available.

The purpose of the cup is to provide reinforcement for the acetabular socket and facilitate bone grafting in cases of severely deficient acetabulum. The pelvic bone grafts are protected form stress overload and potential collapses with the cup. This device can potentially resist acetabular migration by serving as a connection between host bone and to host bone.

There are several different options with the use of a hook and flanges. The flanges come in three different sizes, the blade in two and the hook in one. The use of 6.5-mm low profile screws is used to secure the flanges, hooks and cup in place.

Any polyethylene ring-loc liner may be used with this system. The liner may be placed anteverted to correct anatomic position within the cage if need be.

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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:

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

SUBSTANTIAL EQUIVALENCE: The Modular Protrusio Recovery Cup is substantially equivalent to other acetabular cage devices on the market in overall design and intended function. The following devices are predicates to the Modular Protrusio Cup: Biomet's Modular Acetabular Reconstructive System (M.A.R.S) (K911718), Biomet's Healy Revision Component System (K921139), Biomet's Recovery protrusio Cage (K971890), Osteonics' Restoration GAP Acetabular Cup (K943549), and Intermedics' Orthopaedics' Burch/Schneider Reinforcement Cage (K960678).

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.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K990032
Modular Protrusio Cup
Regulatory Class: II
Product Code: JDI
Dated: December 30, 1998
Received: January 6, 1999

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,

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): K990032

DEVICE NAME: **Modular Protrusio Cup**

INDICATIONS FOR USE:

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1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

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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 K990032