K 971890

SUMMARY OF SAFETY AND EFFECTIVENESS

AUG - 7 1997

Sponsor: Biomet, Inc.
Airport Industrial Park
Warsaw, Indiana 46580

Device: Recovery® Protrusio Cage

Classification: Hip joint metal/polymer semi-constrained cemented prosthesis (88.3350).

Intended Use: The Recovery Protrusio Cage is intended for use in reconstruction of the hip joint due to disease, deformity of trauma.

The device is intended for cemented application for general use in skeletally mature individuals undergoing primary or secondary revision surgery.

The device is a single use implant.

The device is to be used in conjunction with any commercially available all polyethylene acetabular cup.

Device Description: The Recovery Protrusio Cage is a hemispherical metallic cage. This malleable commercially pure (CP) titanium cage can be shaped by the surgeon intraoperatively to fit the proper shape of the patient's anatomy. The surface of the device has a grit blasted (roughened) finish for adherence of bone cement.

The purpose of the cage is to provide reinforcement for the acetabular socket and facilitate bone grafting in cases of a severely deficient acetabulum.[1-4] The pelvic bone grafts are protected from stress overload and potential collapse with the cage. This device can potential resist acetabular migration by serving as a connection between host bone to host bone.[1]

The dome of the cage contains five or six screw holes for component fixation. Two large "windows" in the dome allow for morselized bone impaction and a continuous cement mantle lateral and medial of the device. An anterior cut-out in the dome allows retroverted positioning of the cage without causing impingement of the neck and possible dislocation.

A large ilium flange contains six screw holes for component fixation. This flange is designed for a severely deficient acetabulum to allow engagement of the cage to host bone. An inferior obturator foramen hook is positioned beneath the "teardrop" of the ischium to provide further stability of the cage. The ilium flange and the obturator foramen hook can be shaped by the surgeon to properly fit the patient's anatomy.

The use of 6.5mm low profile screws placed through any (at least two) or all holes in the dome and large ilium flange provide immediate stable fixation of the shell to the pelvis. Adjunctive fixation is achieved with bone cement that adheres an all polyethylene

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acetabular cup into the shell. The all polyethylene acetabular cup is anteverted to the correct anatomic position within the Recovery cage.

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 components	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 Recovery Protrusio Cage is substantially equivalent to other acetabular cage devices on the market in overall design and intended function. Previously 510(k) cleared competitive acetabular components include:

Protek® Acetabular Roof Reinforcement Ring (Intermedics Orthopedics, Inc., Austin, TX) - 510(k) K953578

Bursch/Schneider Reinforcement Cage (Intermedics Orthopedics, Inc., Austin, TX) - 510(k) K960678

Protrusion Cages (Depuy, Warsaw, IN) - 510(k) K962007

Restoration™ GAP Acetabular Cup (Osteonics, Allendale, NJ) - 510(k) K943549

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Deborah M. Matarazzo, R.N., B.S.N.
Clinical Research Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

AUG - 7 1997

Re: K971890
Recovery Protrusio Cage
Regulatory Class: II
Product Code: JDI
Dated: May 19, 1997
Received: May 22, 1997

Dear Ms. Matarazzo:

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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): K971890

Device Name: Recovery Protrusio Cage

Indications For Use: The Recovery Protrusio Cage is intended for use in reconstruction of the hip joint due to disease, deformity of trauma. The device is intended for cemented application for general use in skeletally mature individuals undergoing primary or secondary revision surgery. The device is a single use implant. The device is to be used in conjunction with any commercially available polyethylene acetabular cup.

(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 K971890

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)