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Summary of Safety and Effectiveness
PCA® 36mm Femoral Heads

Proprietary Name:	PCA® 36mm Femoral Heads
Common Name:	Modular Femoral Head Components
Classification Name and Reference:	Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR §888.3350 Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR §888.3358
Device Product Code:	87 JDI, 87 LPH
For Information Contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	April 27, 2006

Description:

This 510(k) submission is a line extension intended to add 36mm femoral heads to the PCA® Femoral Head Components.

Intended Use:

The modifications do not alter the intended use of the predicate system as cleared in the referenced premarket notifications. The subject and predicate devices are single use, sterile femoral heads intended to be used as a modular component as part of a femoral prosthesis. The indications for use for the PCA® 36mm Femoral Heads follow.

Indications for Use:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis (except the Osteolock™ HA Acetabular Cup);
- Correction of functional deformity;

- Revision procedures where other treatments or devices have failed; and,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence:

The subject PCA® 36mm Femoral Heads share the same design, intended use, performance, materials, and operational principle as that of the currently available PCA® Femoral Heads. An engineering analysis demonstrated the subject device falls within pre-established acceptance criteria of the predicate components and are substantially equivalent to these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2006

Howmedica Osteonics Corporation
c/o Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K061168
Trade/Device Name: PCA® 36mm Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: May 26, 2006
Received: May 30, 2006

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

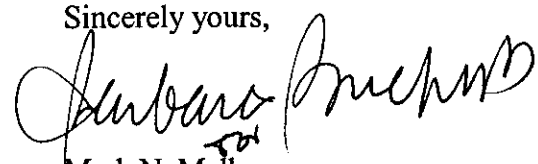
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061168

510(k) Number (if known):

Device Name: PCA® 36mm Femoral Heads

Indications for Use:

- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis (except the Osteolock™ HA Acetabular Cup);
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061168