BIOMET K071053 (pg 1/1)

510(k) Summary

Preparation Date: April 12, 2007

JUN 29 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl
Regulatory Specialist

Proprietary Name: ReCap® HA Press-Fit Femoral Resurfacing Head

Common Name: Hemi-hip femoral prosthesis

Classification Code/Name: KXA, Hip joint femoral (hemi-hip) metallic resurfacing prosthesis (21 CFR 888.3400)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Press-Fit Head resurfacing Device (K023188)

Device Description: The ReCap® HA Press-Fit Femoral Resurfacing Head is a single-use, hemi-hip femoral resurfacing head, designed to replace the outer surface of a natural femoral head, while preserving as much natural bone as possible.

Indications for Use:
Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis, and rheumatoid arthritis.

The device is a single use implant intended for press-fit application.

Summary of Technologies: Except for the additional hydroxyapatite (HA) coating and minor design modifications, the indications for use and technological characteristics (materials, fundamental design, sizing) of the ReCap® HA Press-Fit Femoral Resurfacing Head are identical to the predicate device.

Non-Clinical Testing: Mechanical testing, engineering analysis, and cadaver studies have provided justification for the modifications of this device.

Clinical Testing: No clinical testing was required for this device.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Dr.
Warsaw, IN 46582

ORDER
574.267.6639

FAX

E-MAIL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

Biomet Manufacturing Corp.
% Ms. Becky Earl
Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K071053
Trade/Device Name: ReCap® HA Press-Fit Femoral Resurfacing Head
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis
Regulatory Class: II
Product Code: KXA
Dated: June 7, 2007
Received: June 8, 2007

Dear Ms. Earl:

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.

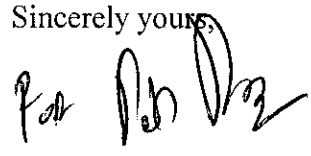
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Indications for Use

510(k) Number (if known): K071053 (pg. 1/1)

Device Name: ReCap® HA Press-Fit Femoral Resurfacing Head

Indications For Use:

Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis, and rheumatoid arthritis.

The device is a single use implant intended for press-fit application.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-USE ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K071053