DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FEB - 9 2006

Ms. Tracy Bickel Johnson, RAC
Manager of Regulatory Affairs
Biomet, Inc.
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K051843
Trade/Device Name: Copeland™ EAS Humeral Resurfacing Heads
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Codes: HSD, KWS, KWT, MBF
Dated: July 5, 2005
Received: July 7, 2005

Dear Ms. Johnson:

This letter corrects our substantially equivalent letter of September 29, 2005.

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/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting 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): K051843

Device Name: Copeland™ EAS Humeral Resurfacing Heads

Indications For Use:

The Copeland™ Extended Articulating Surface (EAS) Resurfacing Heads are indicated for hemi- or total shoulder replacement in patients with massive, irreparable rotator cuff tears and arthritis. Specific indications include:

1) Cuff tear arthropathy.
2) Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

Implants with Interlok®/hydroxyapatite coating are cleared for uncemented applications. Implants with MacroBond® and MacroBond® coating with hydroxyapatite are cleared for cemented and uncemented applications; however, cement should only be applied to the surfaces that do not contain hydroxyapatite coating (i.e. stem).

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson

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

510(k) Number K051843

SEP 2 9 2005

510(k) Summary

Sponsor: Biomet Manufacturing, Corp.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy Bickel Johnson, RAC
Manager, Regulatory Affairs
Biomet Manufacturing Corp.
(574) 267-6639

Proprietary Name: Copeland™ EAS Humeral Resurfacing Heads

Common Name: Resurfacing head

Classification Name(s):

- Prosthesis, shoulder, semi-constrained, metal/polymer cemented (888.3660)
- Prosthesis, shoulder, non-constrained, metal/polymer uncemented (888.3650)
- Prosthesis, shoulder, semi-constrained, metal/polymer uncemented (888.3670)
- Prosthesis, shoulder, hemi-, humeral, metallic uncemented (888.3690)

Substantially Equivalent Devices: Bio-Modular® EAS Heads- K030710 (Biomet); Copeland™ Resurfacing Heads - K010657 (Biomet); Global™ Advantage Extended Humeral Heads – K000575 (DePuy); Global™ C.A.P. Resurfacing Replacement Shoulder- K031971 (DePuy)

Device Description:
These devices are intended for use in patients with an irreparable rotator cuff as a shoulder replacement system that requires minimal bone resection. The Co-Cr-Mo Copeland™ EAS Resurfacing Heads can be used in hemi- or total shoulder replacement surgical procedures in patients experiencing pain and disability of the gleno-humeral joint. By preserving the bone stock, this device gives a patient an alternative to other total shoulder devices where more bone is removed. This device can easily be revised to a longer stemmed prosthesis, if necessary, due to the initial bone preservation.

The humeral head components are available in eight (8) sizes (1-8). The Copeland™ EAS Resurfacing Heads have a variable spherical radii that range fro 20mm to 27mm. The stem is tapered and fluted to provide maximum stability in the humerus.

The most notable landmark on the Copeland™ EAS Humeral Resurfacing Head is the addition of material to the superior-lateral side of the resurfacing head. This material is added to keep the implant surface in contact with the acromion longer, reducing pain and increasing the amount that the arm can be raised in patients with rotator cuff deficiency.

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Biomet Manufacturing Corp.
Copeland™ EAS Humeral Resurfacing Heads

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Summary of Technologies: Combined designs (Bio-Modular® EAS Heads- K030710 and Copeland™ Resurfacing Heads - K010657) were used to develop the Copeland™ Extended Articulating Surface (EAS) Resurfacing Heads.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.
