

K072804 (pg 1 of 2)



**510(k) Summary**

**Preparation Date:** December 3, 2007

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Patricia Sandborn Beres  
Senior Regulatory Specialist

DEC 12 2007

**Proprietary Name:** Comprehensive® RS Shoulder System

**Common Name:** Shoulder replacement components

**Classification Name:**

- Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis (21 C.F.R. 888.3660) KWS

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

- Delta Shoulder and CTA™ Humeral Cups (DePuy) K021478, K050315
- Aequalis® Reversed Shoulder Prosthesis (Tornier) K030941, K041873
- Encore reverse Shoulder Prosthesis (Encore) K041066, K051075
- Zimmer Trabecular Metal™ Reverse Shoulder System K052906
- Bio-Modular® Shoulder System (Biomet) K992119, K030710, K043100

**Device Description:** The Comprehensive® RS Shoulder System is intended for total shoulder replacement in a reverse shoulder.

**Intended Use:**

The Comprehensive® RS Shoulder System is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

A cemented humeral stem must be used.

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.9500  
Office: 574.267.8639  
Main Fax: 574.267.8137  
www.biomet.com

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

K072804 (pg 2 of 2)

The MacroBond®/HA RS Cleats are indicated only for uncemented biological fixation applications. The GT Baseplate components are intended for cementless application with the addition of screw fixation.

**Summary of Technologies:** The Comprehensive® RS Shoulder System have similar technologies as the predicate devices.

**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.

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*All trademarks of property of Biomet, Inc. except for the following:  
Delta CTA is a trademark of Depuy  
Aequalis is a trademark of Tornier S.A. Corporation  
Trabecular Metal are trademarks of Zimmer Trabecular Metal Technology, Inc*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 12 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet Manufacturing Corporation  
c/o Ms. Patricia S. Beres  
56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581

Re: K072804  
Trade/Device Name: Comprehensive® RS Shoulder System  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: KWS  
Dated: September 28, 2007  
Received: October 1, 2007

Dear Ms. Beres:

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.

Page 2 – Ms. Patricia S. Beres

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 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

## Indications for Use

510(k) Number (if known): K072804

Device Name: Comprehensive® RS Shoulder System

### Indications For Use:

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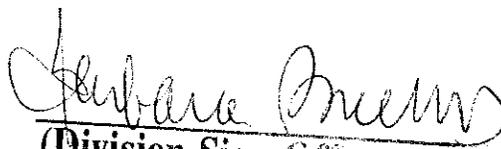
Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  NO   
(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)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K072804 Page 1 of 1