

Summary of Safety and Effectiveness  
Smith & Nephew, Inc. PROMOS® Reverse Shoulder System

SEP - 5 2008

K081016

**Contact Person and Address**

Jason Sells  
Project Manager, Regulatory Affairs  
Smith & Nephew, Inc.  
Orthopaedic Division  
1450 East Brooks Road  
Memphis, Tennessee 38116  
T (901) 399-5520

**Date of Summary:** July 14, 2008

**Name of Device:** Smith & Nephew, Inc. PROMOS® Reverse Shoulder System

**Common Name:** Shoulder Prosthesis

**Device Classification Name and Reference:** 21 CFR 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis

**Device Class:** Class II

**Panel Code:** Orthopaedics/87 HSD

**Device Description**

Subject of this Traditional 510(k) premarket notification is the PROMOS Reverse Shoulder System. The glenohumeral articulation of the Promos Reverse Shoulder is inverted – or reversed – when compared to traditional total shoulder prostheses. Unlike traditional total shoulder prostheses, the Promos Reverse Shoulder is designed so that the "ball" component of the shoulder is assembled to the glenoid baseplate and the "cup" component is assembled onto the humeral stem.

**Mechanical and Clinical Data**

A review of the mechanical and clinical data indicates that the implant components of the Promos Reverse Shoulder System are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

**Intended Use**

The PROMOS Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previous failed joint replacement with a grossly deficient rotator cuff joint.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The glenoid baseplate is intended for cementless application with the addition of screws for fixation.

The humeral stem and body components are intended for cementless use.

The implants of the PROMOS Reverse Shoulder System are single use devices.

**Substantial Equivalence Information**

The substantial equivalence of the Promos Reverse Shoulder System is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – PLUS Orthopedics AG's PROMOS Modular Shoulder System (K063578), Depuy Orthopedics' DELTA CTA Reverse Shoulder Prosthesis (K021478), the Tornier S.A.S. Aequalis Reverse Shoulder Prosthesis (K041873), the Encore Medical Reverse Shoulder Prosthesis System (K041066), and Zimmer's Anatomical Inverse/Reverse Shoulder (K053274).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Smith & Nephew, Inc.  
% Mr. Jason Sells  
Manager, Regulatory Affairs  
Orthopaedic Division  
1450 East Brooks Road  
Memphis, Tennessee 38116

SEP - 5 2008

Re: K081016

Trade/Device Name: Smith & Nephew, Inc. PROMOS Reverse Shoulder System  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: II  
Product Code: KWS  
Dated: August 18, 2008  
Received: August 19, 2008

Dear Mr. Sells:

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 (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 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 – Mr. Jason Sells

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 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): K081016

Device Name: Smith & Nephew, Inc. PROMOS® Reverse Shoulder System

Indications for Use:

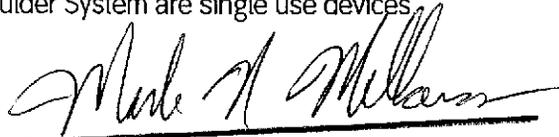
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**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

510(k) Number                     K081016                    

Prescription Use           X           AND/OR Over-The-Counter Use                       
(Part 21 CFR 801 Subpart D) (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)