K053274

JAN 25 2006

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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dalene T. Binkley, RAC Senior Associate, Regulatory Affairs Telephone: (574) 372-4907 Fax: (574) 372-4605
Date:	January 18, 2006
Trade Name:	*Anatomical Shoulder*™ Inverse / Reverse
Common Name:	Total Shoulder Prosthesis
Classification Names and references:	1. Prosthesis, shoulder, semi-constrained, metal/polymer cemented (KWS) - 888.3660 2. Shoulder joint metal/polymer non-constrained cemented prosthesis (KWT) - 888.3650
Predicate Devices:	• Tornier Aequalis Reversed Shoulder Prosthesis, K041873, cleared August 25, 2004 • DePuy Orthopaedics Delta Shoulder, K021478, cleared November 18, 2003 • Encore Medical Encore Reverse Shoulder Prosthesis, K041066, cleared March 24, 2005 • Centerpulse Orthopaedics Anatomical Shoulder System with Removable Heads, K030259, cleared April 24, 2003.
Device Description:	The *Anatomical Shoulder* Inverse / Reverse system is a reverse shoulder prosthesis that allows an intra-operative change from a conventional shoulder arthroplasty to a reverse shoulder arthroplasty. The components of the system include a glenoid fixation baseplate, a glenoid head, a humeral cup and a humeral inlay. These components are intended for use with previously submitted polyaxial screws and previously cleared humeral stems.

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Intended Use:	The *Anatomical Shoulder* Inverse /Reverse system is indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. 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 *Anatomical Shoulder* primary humeral stem is intended for cemented or cementless use. The *Anatomical Shoulder* revision humeral stem is intended for cemented use only. The *Anatomical Shoulder* Inverse /Reverse glenoid fixation is intended for cementless, press-fit use. It requires screws for initial fixation.
Comparison to Predicate Devices:	The *Anatomical Shoulder* Inverse /Reverse system is substantially equivalent to the predicate devices in regards to its intended use, design, size ranges, materials and manufacturing methods.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Analysis of the glenoid components, the glenoid taper connection, glenoid fixation screw stability, the humeral taper connection, the humeral cup and the connection between the humeral cup and the humeral inlay indicate that all components are adequate for their intended use. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2006

Zimmer GMBH
C/O Dalene Binkley
Zimmer, Inc
P.O. Box 708
Warsaw, Indiana 46581

Re: K053274
Trade/Device Name: Anatomical Shoulder™ Inverse / Reverse
Regulation Number: 21 CFR 888.3660
Regulation Name: Prosthesis, Shoulder, semi-constrained, metal/polymer cemented
Regulatory Class: II
Product Code: KWS, KWT
Dated: November 22, 2005
Received: November 23, 2005

Dear Ms. Binkley:

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) 276-0210. 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

K053274

Indications for Use

510(k) Number (if known):

Device Name:

Anatomical Shoulder™ Inverse / Reverse system

Indications for Use:

The *Anatomical Shoulder* Inverse /Reverse system is indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

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 *Anatomical Shoulder* primary humeral stem is intended for cemented or cementless use. The *Anatomical Shoulder* revision humeral stem is intended for cemented use only. The *Anatomical Shoulder Inverse /Reverse* glenoid fixation is intended for cementless, press-fit use. It requires screws for initial fixation.

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)

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

510(k) Number K053274