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OCT 31 2006

Summary of Safety and Effectiveness

Submitter:	Zimmer GmbH P.O. Box CH-8404 Winterthur, Switzerland
Contact Person:	Mason W. Robbins Regulatory Affairs Specialist, Regulatory Affairs Telephone: (574) 371-8065 Fax: (574) 372-4605
Date:	July 17, 2006
Trade Name:	Anatomical Shoulder™ Fracture System
Common Name:	Hemi- and Total Shoulder Arthroplasty Prosthesis
Classification Name and Reference:	prosthesis, shoulder, semi-constrained, metal/polymer cemented; 21 CFR § 888.3660; prosthesis, shoulder, hemi-, humeral, metallic uncemented, 21 CFR § 888.3690
Predicate Devices:	Aequalis Shoulder Fracture System & Aequalis Shoulder, manufactured by Tornier S.A., K060209, cleared March 2, 2006 Global Fx Humeral Stem and Global Advantage Humeral Head, manufactured by Depuy Orthopedics, Inc., K984541, cleared January 14, 1999. Zimmer Trabecular Metal™ Reverse Shoulder System, manufactured by Zimmer, Inc., K052906, cleared December 19, 2005. *Anatomical Shoulder*, manufactured Zimmer GmbH (Formerly Centerpulse Orthopedics), K030259, cleared April 24, 2003.
Device Description:	The *Anatomical Shoulder* Fracture System is designed specifically to treat complex 3 or 4 part proximal humerus fractures requiring hemi- or total shoulder arthroplasty. The *Anatomical Shoulder* Fracture System may be used with or without bone cement. The *Anatomical Shoulder* Fracture System

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consists of four components, a stem, baseplate, screw and head. The *Anatomical Shoulder* Fracture System baseplate offers right and left side-specific versions in order to appropriately match the original shoulder anatomy with respect to right and left humeral anatomy.

The *Anatomical Shoulder* Fracture System head is also designed to articulate with the glenoid components of the *Anatomical Shoulder* System (K030259). The *Anatomical Shoulder* Fracture System stem is also designed to accept the *Anatomical Shoulder* Inverse/Reverse humeral cup (K053274) for conversion from hemi- or total shoulder arthroplasty to an inverse/reverse shoulder arthroplasty in situations when the rotator cuff is irreparable and the patient is experiencing severe instability of the shoulder joint.

The *Anatomical Shoulder* Fracture System stem is comparable in shape and size to stems traditionally used for hemi- and total shoulder arthroplasty. The *Anatomical Shoulder* Fracture System stem, however, has two features which distinguish it as a stem designed for treatment of proximal humeral fractures. The proximal surface of the humeral stem and much of the surface of the baseplate offer spikes which assist in the stable anchoring of the humeral tuberosities to the stem and allow for primary stability of the tuberosities. The *Anatomical Shoulder* Fracture System stem and baseplate also offer several suture holes to allow initial stable fixation of the humeral tuberosities with sutures.

Comparison to Predicate Devices:

The *Anatomical Shoulder* Fracture 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: Performance testing indicates that all components meet or exceed predetermined performance criteria for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2006

Zimmer, Inc
% Mr. Mason W. Robbins, MS, RPCV, CCRP
Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K062029
Trade/Device Name: Anatomical Shoulder™ Fracture System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS, HSD
Dated: October 13, 2006
Received: October 16, 2006

Dear Mr. Robbins:

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, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name:

Anatomical Shoulder™ Fracture System

Indications for Use:

The Anatomical Shoulder™ Fracture System is intended for use in prosthetic replacement of the proximal humerus and the glenoid articular surface of the scapula during total-, hemi- and fracture shoulder arthroplasty in treatment of the following:

- Complex 3 and 4 part fractures of the proximal humerus with subluxation of the head fragment;
- Complex 3 and 4 part fractures of the proximal humerus with loosening of the spongiosa in the head fragment;
- Complex 3 and 4 part fractures of the proximal humerus with additional cross split of the head fragment;
- Fracture instability after osteosynthesis of 3 and 4 fragments of the proximal humerus;
- Posttraumatic necrosis of the humeral head;
- Posttraumatic arthrosis after humeral head fracture.

The *Anatomical Shoulder* Fracture stem is intended for cemented or cementless use.

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 K062029