Summary of Safety and Effectiveness

MAY 19 2006

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dalene T. Binkley Senior Associate, Regulatory Affairs Telephone: (574) 372-4907 Fax: (574) 372-4605
Date:	March 14, 2006
Trade Name:	*Zimmer Trabecular Metal*™ Reverse Shoulder System, Sizes 8mm and 10mm
Common Name:	Total-Shoulder System and Hemi-Shoulder System
Classification Name and Reference:	1. Prosthesis, Shoulder, Semi-constrained, metal/polymer cemented (KWS) 2. Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (HSD) 3. Shoulder joint metal/polymer non-constrained cemented prosthesis (KWT) 21 CFR § 888.3660, 888.3690 and 888.3650
Predicate Device:	*Zimmer Trabecular Metal*™ Reverse Shoulder System, manufactured by Zimmer, Inc., 510(k) K052906, cleared December 19, 2005.
Device Description:	The *Zimmer Trabecular Metal*™ Reverse Shoulder System is a modular total shoulder prosthesis that was designed specifically to include patients with non-functional rotator cuffs. It was developed to either encompass a traditional shoulder prostheses, a reverse design or be transformed into a hemi-prosthesis depending on clinical cases encountered during the surgical procedure.

Intended Use:

The *Zimmer Trabecular Metal* Reverse Shoulder System is indicated for the following:

Reverse application:

- the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
- ununited humeral head fractures of long duration;
- irreducible 3-and 4-part proximal humeral fractures;
- avascular necrosis of the humeral head, or other difficult clinical management problems (such as a failed total shoulder arthroplasty or grossly rotator cuff deficient joint) where arthrodesis or resectional arthroplasty is not acceptable.

Hemiarthroplasty/Total application:

- the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
- ununited humeral head fractures of long duration;
- irreducible 3-and 4-part proximal humeral fractures;
- avascular necrosis of the humeral head, or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component or reverse components for total shoulder arthroplasty (conventional or reverse applications).

The *Trabecular Metal* humeral and reverse base plate components are intended for either cemented or uncemented use. The reverse base plate requires two screws for initial fixation.

Comparison to Predicate Device:

The *Zimmer Trabecular Metal* Reverse Shoulder System, Sizes 8mm and 10mm are packaged, manufactured, and sterilized using the same or similar materials and processes as the predicate

	device. The subject device also has similar intended use and fixation methods as the predicate device.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the *Zimmer Trabecular Metal* Reverse Shoulder System, Sizes 8mm and 10mm are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

Zimmer, Inc
c/o Ms. Dalene T. Binkley
Senior Associate, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K060704
Trade/Device Name: *Zimmer Trabecular Metal* Reverse Shoulder System, Sizes 8mm and 10mm
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, KWT
Dated: April 25, 2006
Received: April 24, 2006

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) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Herbert Lerner MD

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060704

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer Trabecular Metal Reverse Shoulder System, Sizes 8mm and 10mm

Indications for Use:

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Reverse application:

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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 K060704