K041549 1/2

SEP - 1 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dalene T. Binkley, RAC Associate, Regulatory Affairs Telephone: (574) 372-4907 Fax: (574) 372-4605
Date:	August 27, 2004
Trade Name:	*Zimmer Trabecular Metal*™ Humeral Stem
Common Name:	Total Shoulder System
Classification Name and Reference:	Shoulder joint metal/polymer non-constrained cemented prosthesis. 21 CFR § 888.3650 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis. 21 CFR § 888.3690
Predicate Device:	The predicate and design basis for the *Zimmer Trabecular Metal*™ Humeral Stem is the New Zimmer Shoulder System (Bigliani/Flatow) (K982981, cleared Dec.17, 1998) and the Bio-Modular Shoulder System by Biomet, Inc. (K992119, cleared Sept. 13, 1999).
Device Description:	The *Zimmer Trabecular Metal* Humeral Stem is intended to be a single use only implant that is used to replace a shoulder joint. This humeral stem uses Trabecular Metal around the proximal part of the stem for biological ingrowth. It also has an anti-rotational fin, a proximal stem collar, suture holes, and a distal fluted stem body. Stems are available in sizes ranging in diameter from 9-18mm and in the lengths of 130mm and 170mm.

Intended Use:	Prosthetic replacement with this device may be indicated for 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 arthoplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights of 27mm or greater may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable.
Comparison to Predicate Device:	The *Zimmer Trabecular Metal* Humeral Stem is packaged, manufactured, and sterilized using the same materials and processes as the predicate devices. The subject device also has the same intended use and fixation methods as the predicate devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the *Zimmer Trabecular Metal* Humeral Stem is 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

SEP - 1 2004

Ms. Dalene Binkley, RAC
Associate, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581

Re: K041549
Trade/Device Name: Trabecular Metal Humeral Stem
Regulation Number: 21 CFR 888.3650; 21 CFR 888.3690
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis;
Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: June 3, 2004
Received: June 9, 2004

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.

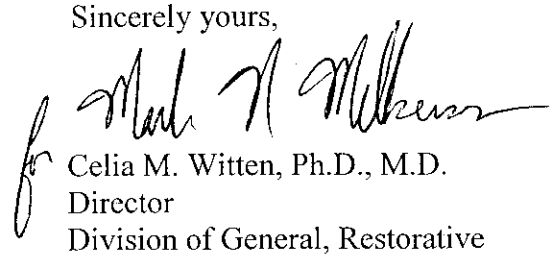
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
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:

Zimmer Trabecular Metal™ Humeral Stem

Indications for Use:

Prosthetic replacement with this device may be indicated for 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 arthoplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights of 27mm or greater may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable.

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)

Division of General
Division of General, Restorative
and Neurological Devices

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