K103404 (1/4)

zimmer

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Summary of Safety and Effectiveness

MAR 15 2011

Sponsor:	Zimmer GmbH SulzerAllee 8 CH-8404 Winterthur, Switzerland
Contact Person:	Jason Heckaman Associate Manager, Regulatory Affairs Telephone: (574) 371-8675 Fax: (574) 372-4605
Date:	February 25, 2011
Trade Name:	*Anatomical Shoulder*™ Combined System
Product Code / Device:	KWT – Prosthesis, Shoulder, Non-constrained, Metal/Polymer Cemented KWS - Prosthesis, Shoulder, Semi-constrained, Metal/Polymer Cemented HSD – Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Regulation Number / Description:	21 CFR § 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis. 21 CFR § 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3690 - Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Predicate Device:	*Anatomical Shoulder* with Removable Head, manufactured by Zimmer GmbH, K030259, cleared 04/24/2003 *Anatomical Shoulder* Fracture System, manufactured by Zimmer GmbH, K062029, cleared October 31, 2006) *Bigliani/Flatow*® The Complete Shoulder System, manufactured by Zimmer, Inc., K982981, cleared 12/17/1998; *Trabecular Metal* Glenoid, manufactured by Zimmer TMT, K022377, cleared 12/10/2002

Device Description:

The *Anatomical Shoulder* (AS) Combined System consists of the following:

- AS Humeral Stem (cemented or uncemented)
- AS Fracture Humeral Stem
- *Bigliani/Flatow* Head
- *Bigliani/Flatow* Gleniod
- *Trabecular Metal* (TM) Glenoid
- AS *Bigliani/Flatow* (AS B/F) Adaptor

The AS B/F Adaptor is a new product designed to be used with the humeral stems of the *Anatomical Shoulder* System and *Anatomical Shoulder* Fracture System and with any humeral head of the *Bigliani/Flatow* (BF) System in a conventional hemi or total shoulder arthroplasty procedure. The B/F humeral heads are used with existing UHMWPE B/F glenoids and TM glenoids manufactured from *Trabecular Metal* and UHMWPE. AS cemented humeral stems are manufactured from *Protasul*®-1 (Co-Cr-Mo); the uncemented and fracture stems from *Protasul*-100 (titanium alloy). The B/F heads are manufactured from *Zimaloy*® (Co-Cr-Mo). Collectively, these components are identified as the *Anatomical Shoulder* Combined System.

The Adaptor features two taper interfaces, one connecting to the *Anatomical Shoulder* humeral stems and the other connecting to the *Bigliani/Flatow* humeral heads. The proximal taper of the adaptor (connecting to the *Bigliani/Flatow* heads) is identical to the male taper geometry from the predicate *Bigliani/Flatow* humeral stems. The distal taper of the adaptor (connecting to the *Anatomical Shoulder* humeral stem) is a male oval taper, identical to the oval taper of the predicate *Anatomical Shoulder* Ball-Taper component. Both the AS B/F Adaptor and the predicate AS Ball-Taper component are manufactured from *Protasul*-100, a forged titanium alloy.

Intended Use:

Advanced destruction of the shoulder joint resulting from:

- Omarthrosis.
- Rheumatoid arthritis

- Post-traumatic arthritis
- Avascular necrosis of the humeral head
- Cuff-tear arthropathy (BF heads with heights of 27mm or greater)
- Conditions following earlier operations (including revision shoulder arthroplasty).

The *Anatomical Shoulder* Combined System is intended for cemented or cementless use.
When used with the following humeral stems the *Anatomical Shoulder* Combined System is intended for cemented use:

- *Anatomical Shoulder* Standard Cemented Humeral Stem.
- *Anatomical Shoulder* Revision Stem.

When used with the following humeral stem the *Anatomical Shoulder* Combined System is intended for cementless use:

- *Anatomical Shoulder* Standard Uncemented Stem.

When used with the following humeral stems the *Anatomical Shoulder* Combined System is intended for cemented or cementless use:

- *Anatomical Shoulder* Fracture Stem.
- *Anatomical Shoulder* Fracture Long Stem.

When used with the following glenoids the *Anatomical Shoulder* Combined System is intended for cemented use:

- *Bigliani/Flatow* Glenoid (pegged and keeled).
- *Trabecular Metal* Glenoid.

Comparison to Predicate Device:

The proposed *Anatomical Shoulder* Combined System consists of some of the same devices as the referenced predicates, including: *Anatomical Shoulder* humeral stems, *Bigliani/Flatow* humeral heads and glenoids, and the *Trabecular Metal* glenoid. Additionally, the new AS B/F component has identical proximal taper geometry to that of the predicate *Bigliani/Flatow* humeral stem and identical distal taper geometry to that of the predicate *Anatomical Shoulder* Ball-Taper component. Collectively, the proposed system has the same intended use, has similar performance

	characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing and/or analyses demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing and/or analyses included: Evaluation of Loading Conditions, Fatigue Analysis, Fretting Corrosion, Assembly Strength Test. 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer GmbH
% Zimmer, Inc.
Mr. Jason Heckaman
P.O Box 708
Warsaw, Indiana 46581-0708

MAR 15 2011

Re: K103404
Trade/Device Name: Anatomical Shoulder™ Combined System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWT, KWS, HSD
Dated: February 25, 2011
Received: February 28, 2011

Dear Mr. Heckaman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K103404

Device Name:
Anatomical Shoulder™ Combined System

Indications for Use:
Advanced destruction of the shoulder joint resulting from:

- Omarthrosis.
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- *Trabecular Metal* Glenoid.

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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103404