Summary of Safety and Effectiveness

Submitter	Zimmer GmbH Sulzer Allee 8 Winterthur, Switzerland CH-8404
Contact Person	Laura D. Williams, RAC Manager, Corporate Regulatory Affairs Telephone: (574) 372-4523 Fax: (574) 372-4605
Date	December 16, 2005
Trade Name	*Durom*® Acetabular Component *Metasul*® *LDH*™ Large Diameter Heads
Common Name	Total hip prosthesis
Classification Name	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Classification Reference	21 CFR § 888.3330
Predicate Devices	• Biomet M^2A Magnum System (K042037) • Wright Metal Transcend Articular System (K021349) • Centerpulse/Zimmer *Epsilon*™ *Metasul*® Acetabular Insert and *Metasul* Modular Femoral Head (K033634)
Device Description	The *Metasul LDH* large diameter head system consists of large diameter femoral heads, *Durom* acetabular components and neck adapters for neck length variation. The *Metasul LDH* femoral heads are made of CoCrMo alloy, and are available in diameters ranging from 38 to 60mm. They are modular in design, and are for use with four head/neck length adaptors (-4 to +8mm), also manufactured from CoCrMo alloy. The femoral heads and neck adapters are compatible with 12/14 taper femoral stems. The *Durom* Acetabular component is a metal monoblock CoCrMo alloy cup with a coating of titanium plasma spray. It is available is sizes from 44 to 66mm, and is intended for press-fit fixation in the acetabulum.

Intended Use	• Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis. • Those patients with failed previous surgery where pain, deformity, or dysfunction persists. • Revision of previously failed hip arthroplasty. Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.
Comparison to Predicate Device	The proposed device 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)	The results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Zimmer GmbH
c/o Ms. Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K053536
Trade/Device Name: *Durom*® Acetabular Component and *Metasul*® *LDH*® Large Diameter Heads
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Codes: KWA
Dated: December 16, 2005
Received: December 19, 2005

Dear Ms. Williams:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K053536

Device Name:

Durom® Acetabular Component
Metasul® *LDH*® Large Diameter Heads

Indications for Use:

- Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

Prescription Use _X_ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative and Neurological Devices

510(k) Number K053536