K091973

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

NOV 17 2009

Sponsor:	Zimmer, GmbH Sulzer Allee 8 Winterthur, CH-8404, Switzerland
Contact Person:	Benjamin Curson, CQE RAC Associate Project Manager, Regulatory Affairs Telephone: (574) 372-4119 Fax: (574) 372-4605
Date:	June 29, 2009
Trade Name:	*Metasul*® Taper Liner and *Metasul* Femoral Heads
Common Name:	Total Hip Prosthesis
Classification Name	KWA – Hip joint metal/metal semi-constrained with uncemented acetabular shell.
Classification Reference:	21 CFR § 888.3330
Predicate Device:	*Inter-Op*™ *Metasul* Acetabular System (K974728), *Epsilon*™ *Metasul* Acetabular 32mm Insert/Femoral Head (K033634), both manufactured by Zimmer, and Depuy Pinnacle Metal-on-Metal Acetabular Cup Liners (K062426), manufactured by Depuy Orthopedics
Device Description:	The *Metasul* Taper Liner and Femoral Heads are composed of CoCrMo alloy. The outer diameter of the liner is machined with a locking taper feature that mates with the interior *Continuum*™ and *Trilogy*® IT acetabular shell's taper. The *Metasul* Taper Liners are designed for use only with *Metasul* Femoral Heads.

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Intended Use:

Noninflammatory degenerative joint disease (NIDJD) including avascular necrosis, osteoarthritis, post-traumatic arthritis and congenital hip dysplasia and inflammatory joint disease (IJD), e.g. rheumatoid arthritis if bone quality is adequate.

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 handicapped 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.

The system is intended for use either with or without bone cement in total hip arthroplasty.

Comparison to Predicate Device:

The *Metasul* Taper Liners and *Metasul* Femoral Heads have the same intended use as the predicate devices. The design features and materials of the subject device are substantially equivalent to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-Clinical testing demonstrated that the *Metasul* Taper liners and *Metasul* Femoral Heads met performance requirements and are as safe and effective as their predicates.

Clinical Performance and Conclusions:

Clinical data demonstrates the safety and effectiveness of the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Zimmer, GmbH
% Zimmer, Inc.
Mr. Benjamin Curson, CQE RAC
Associate Project Manager
Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

NOV 17 2009

Re: K091973
Trade/Device Name: Metasul® Taper Liners, Metasul Femoral Heads
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: October 20, 2009
Received: October 21, 2009

Dear Mr. Curson:

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 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,

for 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):

Device Name:

Metasul® Taper Liners and *Metasul* Femoral Heads

Indications for Use:

- Noninflammatory degenerative joint disease (NIDJD) including avascular necrosis, osteoarthritis, post-traumatic arthritis and congenital hip dysplasia and inflammatory joint disease (IJD), e.g. rheumatoid arthritis if bone quality is adequate.
- 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 handicapped 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.

- The system is intended for use either with or without bone cement in total hip arthroplasty.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Janeta J. for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091973