K071723

MAR - 7 2008

Summary of Safety and Effectiveness

Submitter:	Zimmer GmbH Sulzer Allee 8 Winterthur, Switzerland CH-8404
Contact Person:	Dalene T. Binkley, MS, RAC Senior Associate, Corporate Regulatory Affairs Telephone: 574-372-4907 Fax: (574) 372-4605
Date:	September 24, 2007
Trade Name:	*Zimmer*® *Porolock*® MIS Stem
Common Name:	Total Hip Prosthesis
Classification Name and Reference:	1. KWA - Hip joint metal/metal semi-constrained with uncemented acetabular shell, 21 CFR § 888. 3330 2. JDL - Hip joint metal/metal semi-constrained with cemented acetabular shell, 21 CFR § 888. 3320 3. LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR § 888.3353 4. KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR § 888.3390 5. KWL - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR § 888.3360 6. LWJ - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR § 888.3350 7. JDI – Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR § 888.3310 8. KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis, 21 CFR § 888.33

Predicate Device:

Zimmer M/L Taper Hip Prosthesis, manufactured by Zimmer, Inc., K032726, cleared October 22, 2003.

Durom® Acetabular Component and *Metasul*® *LDH*™ Large Diameter Heads, manufactured by Zimmer GmbH, K053536, cleared March 16, 2006.

Alloclassic® *Zweymueller*® SL/SLL Femoral Stem, manufactured by Zimmer GmbH, K030373, cleared March 6, 2003.

Device Description:

The *Zimmer Porolock* MIS Stem is a modular femoral stem intended for total or hemi-hip arthroplasty. The curved, uncemented stem and is coated proximally with Titanium Vacuum Plasma Sprayed (Ti-VPS) and rough-blasted distally. The 12/14 femoral stem is available in multiple sizes in order to address different patient morphologies.

Intended Use:

This femoral stem is for total or hemi-hip arthroplasty and is indicated for the following conditions:
Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory degenerative 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.

This stem is for uncemented use only.

Comparison to Predicate Device:	The *Zimmer Porolock* MIS 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 Porolock* MIS Stem met performance requirements and 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

MAR - 7 2008

Zimmer GmbH
% Ms. Dalene T. Binkley
Senior Associate, Warsaw Regulatory Affairs
P.O. Box 708
Warsaw, IN 46581-0708

Re: K071723
Trade/Device Name: *Zimmer® Porolock®* MIS Stem
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, KWZ, JDL, LZO, KWY, KWL, LWJ, JDI
Dated: March 3, 2008
Received: March 4, 2008

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.

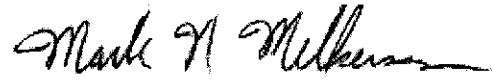
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K071723

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer® *Porolock*® MIS Stem

Indications for Use:

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This stem is for uncemented use only.

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)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071723