K081007 (pg. 1 of 2)

MAY - 6 2008

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

zimmer

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Benjamin C. Curson, CQE Associate, Regulatory Affairs Telephone: (574) 372-4119 Fax: (574) 372-4605
Date:	May 2, 2008
Trade Name:	*Zimmer*® M/L Taper Hip Prosthesis with *Kinectiv*™ Technology System
Common Name:	Total Hip Prosthesis
Classification Name and Reference:	KWA - Hip joint metal/metal semi-constrained with uncemented acetabular shell, 21 CFR § 888.3330
Predicate Device:	*Zimmer*® M/L Taper Hip Prosthesis with Modular Neck Technology, manufactured by Zimmer, Inc., K063251, cleared January 24, 2007.
Device Description:	The *Zimmer* M/L Taper Hip Prosthesis with *Kinectiv* Technology System is a modular, wedge-shaped stem that is coated with Ti-6Al-4V titanium alloy plasma spray.

K081007 (pg. 2 of 2)

	The modular neck options allow for soft tissue balancing and easier restoration of the hip joint center of rotation. The modularity feature will allow surgeons to independently equalize leg length and optimize offset while, at the same time, maximizing joint stability for a variety of patient anatomies.
Intended Use:	Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures. Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected. The femoral stem is for cementless use only.
Comparison to Predicate Device:	The *Zimmer* M/L Taper Hip Prosthesis with *Kinectiv* Technology System is packaged, manufactured, and sterilized using the same materials and processes as its predicate. The subject device also has the same intended use and fixation methods as the predicate device.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the *Zimmer* M/L Taper Hip Prosthesis with *Kinectiv* Technology System met performance requirements and is as safe and effective as its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2008

Zimmer, Inc.
% Mr. Benjamin C. Curson
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K081007
Trade/Device Name: *Zimmer*® M/L Taper Hip Prosthesis with *Kinectiv*™ Technology System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prothesis
Regulatory Class: Class III
Product Code: KWA, JDL, LWJ, LZO, MEH
Dated: April 4, 2008
Received: April 8, 2008

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 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Indications for Use

510(k) Number: K081007

Device Name:

Zimmer® M/L Taper Hip Prosthesis with *Kinectiv*™ Technology System

Indications for Use:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

The femoral stem is for cementless 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 MKM

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

510(k) Number K081007