JUN - 7 2007

K070695

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dalene T. Binkley Senior Associate, Regulatory Affairs Telephone: (574) 372-4907 Fax: (574) 372-4605
Date:	June 4, 2007
Trade Name:	*Zimmer*® Patellofemoral Joint Prosthesis
Common Name:	Knee Prosthesis Component
Classification Name and Reference:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis 21 CFR § 888.3540
Predicate Device:	Stryker Compartmental Knee System, manufactured by Howmedica Osteonics Corp., K052917, cleared December 27, 2005 *Natural-Knee*® II Patellofemoral Joint Prosthesis, manufactured by Zimmer, Inc., K002356, cleared October 30, 2000 *NexGen*® Knee Gender Solutions Female Femoral Components, manufactured by Zimmer, Inc., K060370, cleared April 28, 2006
Device Description:	The *Zimmer* Patellofemoral Joint (PFJ) Prosthesis is designed to closely replicate the anatomic features of the patellar groove on the femur. The implant's articulating surface incorporates the *NexGen*® knee system's frontal profile geometry for optimal patella tracking for both resurfaced and unresurfaced patellas. The construct of the PFJ prosthesis accommodates a wide range of patients, both female and male. Five sizes in left and right configurations

	are being offered for this implant.
Intended Use:	-Osteoarthritis, traumatic arthritis, polyarthritis, and/or severe chondrocalcinosis of the patellofemoral joint; -The salvage of previously failed surgical attempts (e.g., arthroscopy, lateral release, cartilage transplantation); -History of patellar dislocation or patella fracture; -Dysplasia-induced degeneration This device is intended for cemented use only.
Comparison to Predicate Device:	The *Zimmer* Patellofemoral Joint Prosthesis 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 similar fixation methods as the predicate devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the *Zimmer* Patellofemoral Joint Prosthesis 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

JUN - 7 2007

Zimmer, Inc.
% Ms. Dalene T. Binkley M.S., RAC
Senior Associate, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K070695
Trade/Device Name: *Zimmer*® Patellofemoral Joint Prosthesis
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained Cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: March 12, 2007
Received: March 13, 2007

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

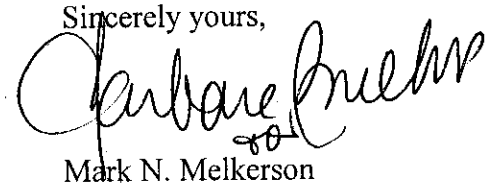
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 toll-free number (800) 638-2041 or (240) 276-3150 or on 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

Indications for Use

510(k) Number (if known): K070695

Device Name:

Zimmer® Patellofemoral Joint Prosthesis

Indications for Use:

-Osteoarthritis, traumatic arthritis, polyarthritis, and/or severe chondrocalcinosis of the patellofemoral joint;
-The salvage of previously failed surgical attempts (e.g., arthroscopy, lateral release, cartilage transplantation),
-History of patellar dislocation or patella fracture;
-Dysplasia-induced degeneration

This device is intended for cemented 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)

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

510(k) Number K070695