K070978 (pg. 1 of 3)

Summary of Safety and Effectiveness

JUL - 3 2007

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Brandon Hipsher, RAC Senior Associate, Corporate Regulatory Affairs Telephone: (574) 371-8083 Fax: (574) 372-4605
Date:	June 20, 2007
Trade Name:	*Zimmer*® Segmental System
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint, femorotibial, metal/polymer, constrained, cemented prosthesis 21 CFR § 888.3510, product code KRO
Predicate Device:	*NexGen*® Complete Knee Solutions Rotating Hinge Knee Systems, manufactured by Zimmer, Inc., K013385, cleared January 9, 2002. Modular Options for Severe Bone Loss and Trauma (*MOST*®) System, manufactured by Zimmer Inc., K002324, cleared August 24, 2000.
Device Description:	The *Zimmer*® Segmental System is a fully constrained cemented knee prosthesis intended to replace the distal femur and/or total knee in cases that require extensive resection and restoration. The Segmental Knee System provides for cross compatibility between selected components from the *MOST* System and the *NexGen* Rotating Hinge Knee Systems. When used with *MOST* System proximal femur and *NexGen* Rotating Hinge Knee tibial baseplates, a total mid-calf to hip replacement can be achieved. The distal femoral components are designed to be compatible with all current *NexGen* patella components.

The Segmental System is a modular system comprised of fluted stem extensions, segments, articular surfaces and distal femoral components. The prosthesis is designed to be used with *NexGen* patellar and tibial components as well as the *MOST* System proximal femoral component.

Intended Use:

This device is indicated for:

- Moderate to severe knee instability
- Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle
- Valgus, varus or flexion deformities
- The salvage of previously failed surgical attempts

- A total femoral replacement construct consisting of *MOST* System proximal femoral, Segmental System segments and Segmental System distal femoral components may be used without cement.
- Fluted stem extensions require the use of either a smooth or *Trabecular Metal* stem collar, which must be cemented to the stem. Following cementing to the stem extension, the smooth collar and the remainder of the stem must also be cemented against the bone.
- The *Trabecular Metal* collar may be used cemented or uncemented against the bone as long as the remainder of the stem extension is cemented.
- All other constructs are for cemented use only.

Comparison to Predicate Device:

This device is packaged, manufactured and sterilized using the same materials and processes as the predicate devices. This device also has the same intended use as predicate devices. The device shares a similar fixation method as the predicate devices. The only difference in fixation methods arise when using the *Trabecular Metal* stem collar, which may be used cemented or uncemented against the bone. All other constructs are for cemented use only.

K070978 (pg 3 of 3)

Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing demonstrate that the device is safe and effective. Clinical Performance and Conclusions: Clinical data were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2007

Zimmer, Inc.
% Mr. Brandon Hipsher, RAC
Senior Associate, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K070978
Trade/Device Name: *Zimmer*® Segmental System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO, JDI, LZO
Dated: April 2, 2007
Received: April 6, 2007

Dear Mr. Hipsher:

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 the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

7 SEP 04 7/2/12

Enclosure

Indications for Use

510(k) Number (if known): K070978

Device Name:

Zimmer® Segmental System

Indications for Use:

- This device is indicated for:
  - Moderate to severe knee instability
  - Significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle
  - Valgus, varus or flexion deformities
  - The salvage of previously failed surgical attempts
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- The *Trabecular Metal* collar may be used cemented or uncemented against the bone as long as the remainder of the stem extension is cemented.
- All other constructs are for cemented use only.

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)

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

510(k) Number K070978