K050105

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MAY 17 2005

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Brandon Hipsher Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8083 Fax: (574) 372-4605
Date:	January 17, 2005
Trade Name:	*NexGen*® Complete Knee Solution Distal Femoral Spacers
Common Name:	Total knee prosthesis
Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3560
Predicate Device:	*ZCA*® All-Poly Acetabular Cup, Snap-In (PMMA spacer) manufactured by Zimmer, Inc., K030153, cleared April 1, 2003.
Device Description:	The Distal Femoral Spacer is a poly(methyl methacrylate) [PMMA] cement spacer designed to help adjust extension gaps and maintain a uniform cement mantle when used with the femoral component of a cemented total knee prosthesis. It is used in pairs; each Distal Femoral Spacer fits over one of the femoral posts. This creates a defined space between the femoral component and the prepared bone, helping maintain a uniform cement mantle. The Distal Femoral Spacers themselves are then incorporated into the cement mantle by the polymerizing bone cement. The Distal Femoral Spacer is available in 2mm and 4mm thicknesses.
Intended Use:	This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

This device is intended for cemented use only.

Comparison to Predicate Device:

The Distal Femoral Spacers are substantially equivalent to the predicate PMMA spacer in that both are manufactured from the same material and are intended to help maintain a uniform cement mantle.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical performance testing was not required for this device.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Mr. Brandon Hipsher
Zimmer Incorporated
345 East Main Street
Warsaw, Indiana 46580

Re: K050105
Trade/Device Name: *Nex Gen*® Complete Knee Solution Distal Femoral Spacers
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial metal/ polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: April 13, 2005
Received: April 14, 2005

Dear Mr. Hipsher:

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 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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):

Device Name:

NexGen® Complete Knee Solution Distal Femoral Spacers

Indications for Use:

This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

This device is intended 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 K050105