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Summary of Safety and Effectiveness

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:	August 15, 2007
Trade Name:	*NexGen*® *Prolong*™ All-Poly Patella
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis 21 CFR § 888.3560
Predicate Device:	*NexGen* Knee System, manufactured by Zimmer, Inc., K933785, cleared January 30, 1995
Device Description:	The proposed device is part of the NexGen system of semiconstrained, nonlinked knee prostheses.
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 indicated for cemented use only.

Comparison to Predicate Device:	Except for a change in material, the *NexGen Prolong* All-Poly Patella is identical to the predicate device. This modification does not change the intended use or fundamental scientific technology.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Performance testing completed as part of the design assurance process demonstrated that this device is safe and effective and is substantially equivalent to the predicate 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

SEP - 6 2007

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

Re: K072281
Trade/Device Name: NexGen® Prolong™ All-Poly Patella
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer Semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 15, 2007
Received: August 16, 2007

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.

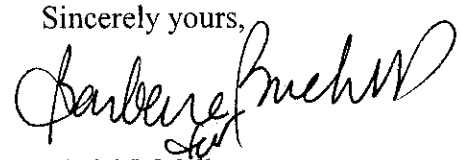
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

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Indications for Use

510(k) Number (if known):

Device Name:

NexGen® *Prolong*™ All-Poly Patella

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 indicated for cemented use only.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (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

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