

**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:** October 12, 2004

**Trade Name:** *NexGen*<sup>®</sup> Complete Knee Solution LPS-Flex  
*Prolong*<sup>™</sup> Highly Crosslinked Polyethylene  
Articular Surfaces

**Common Name:** Total Knee Prosthesis

**Classification Name and Reference:** Knee joint patellofemorotibial polymer/metal/  
polymer semi-constrained cemented prosthesis  
21 CFR § 888.3560 (JWH)  
Knee joint patellofemorotibial metal/polymer  
porous-coated uncemented prosthesis  
21 CFR § 888.3565 (MBH)

**Predicate Devices:** LPS-Flex Fixed Bearing Articular Surface  
Components, manufactured by Zimmer, Inc.,  
K991581, cleared July 30, 1999.

*Prolong* Highly Crosslinked Polyethylene Cruciate  
Retaining (CR) Articular Surface Components,  
manufactured by Zimmer, Inc., K013991, cleared  
December 27, 2001.

*NexGen* Porous, Uncemented Femoral and Tibial  
Baseplate Components, manufactured by Zimmer,  
Inc., K031061, cleared October 9, 2003.

**Device Description:** The *NexGen* LPS-Flex *Prolong* articular surfaces  
are part of the *NexGen* system of semiconstrained,  
nonlinked condylar 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.

The device is indicated for use when both cruciate ligaments have been excised.

The device is intended for use as part of a cemented or uncemented knee prosthesis.

**Comparison to Predicate Device:**

Except for a change in material and minor dimensional modifications, LPS-Flex *Prolong* articular surfaces are identical to the predicate device. The modifications do not change the intended use or the fundamental scientific technology. The device is packaged using the same materials and processes.

**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 substantially equivalent to the predicate device.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 13 2004

Mr. Brandon Hipsher  
Specialist, Corporate Regulatory Affairs  
Zimmer, Inc.  
P.O. Box 708  
Warsaw, Indiana 46581-0708

Re: K042271

Trade/Device Name: NexGen<sup>®</sup> Complete Knee Solution LPS-Flex Prolong<sup>™</sup> Highly  
Crosslinked Polyethylene Articular Surfaces

Regulation Number: 21 CFR 888.3560 and 21 CFR 888.3565

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-  
constrained cemented prosthesis and Knee joint patellofemorotibial  
metal/polymer porous-coated uncemented prosthesis

Regulatory Class: II

Product Code: JWH and MBH

Dated: September 10, 2004

Received: September 13, 2004

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.

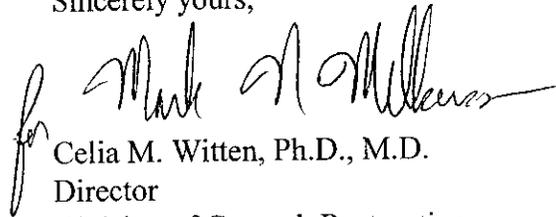
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the printed name.

Celia M. Witten, Ph.D., M.D.  
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): K042271

### Device Name:

*NexGen*<sup>®</sup> Complete Knee Solution LPS-Flex *Prolong*<sup>™</sup> Highly Crosslinked Polyethylene Articular Surfaces

### 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
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The device is indicated for use when both cruciate ligaments have been excised.

The device is intended for use as part of a cemented or uncemented knee prosthesis.

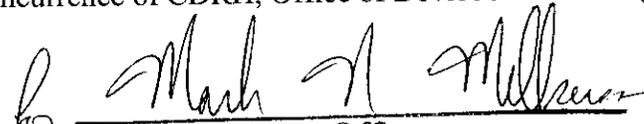
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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 K042271