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K031061

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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	June 30, 2003
Trade Name:	*NexGen*® Porous, Uncemented Femoral and Tibial Baseplate Components
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis - 21 CFR § 888.3565
Predicate Devices:	*NexGen* Complete Knee Solution, manufactured by Zimmer, K933785, cleared January 30, 1995. *NexGen* Complete Knee Solution Cruciate Retaining Flex Femoral Component, manufactured by Zimmer, K023211, cleared October 17, 2002. *NexGen* Complete Knee Solution Legacy Posterior Stabilized (PS) and Constrained Condylar Knee (CCK) Femoral Components and Articular Surfaces, manufactured by Zimmer, K960279, cleared April 26, 1996.
Device Description:	This submission is for the uncemented use of *NexGen* porous total knee prostheses. All have already been cleared for cemented use. - Porous *NexGen* Cruciate Retaining (CR) Femoral Components - Porous *NexGen* CR 4-pegged Tibial Baseplate Components

- Porous *NexGen* Stemmed Tibial Baseplate Components
- Porous *NexGen* CR-Flex Femoral Components
- Porous *NexGen Legacy*® Posterior Stabilized (LPS) Femoral Components

Each of the above devices is part of a semiconstrained, non-linked condylar knee system. The CR devices are for use with a functional posterior cruciate ligament and the LPS device is for use with both cruciate ligaments excised.

Intended Use:

These devices are 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, and 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.

CR, LPS and CR-Flex porous coated femoral or tibial baseplate components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate and all-polyethylene patella components (including HA/TCP coated) are indicated for cemented use only

Comparison to Predicate Device:

These devices are identical to the predicate devices except for the uncemented indication for use.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

No additional testing was required.

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

OCT - 9 2003

Mr. Stephen H. McKelvey
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K031061
Trade/Device Name: *NexGen*® Porous, Uncemented Femoral and Tibial Baseplate Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: July 16, 2003
Received: July 17, 2003

Dear Mr. McKelvey:

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 (301) 594-4659. 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,

for Mark N. Melkerson

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): K031061

Device Name:

NexGen® Porous, Uncemented Femoral and Tibial Baseplate Components

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.

CR, LPS and CR-Flex porous coated femoral or tibial baseplate components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate and all-polyethylene patella components (including HA/TCP coated) are indicated for cemented use only.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sig[illegible])
Division of G[illegible]er[illegible], Restorative
and Neurologi[illegible] [illegible]vices

510(k) Number K031061