K160370 page 1 of 2

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen McKelvey, MA, RAC Manager, Corporate Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	February 10, 2006
Trade Name:	*NexGen*® Knee Gender Solutions Female (GSF) Femoral Components
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint, patellofemorotibial, metal/polymer, semi-constrained, cemented prosthesis 21 CFR § 888.3560
Predicate Devices:	*NexGen* LPS-Flex knee, manufactured by Zimmer, K991581, cleared July 30, 1999 and the *NexGen* CR-Flex femoral component, manufactured by Zimmer, K023211, cleared October 17, 2002
Device Description:	The *NexGen* Knee GSF Femoral Components include both LPS-Flex GSF and CR-Flex GSF versions and are part of the Zimmer Flex-series of semiconstrained, nonlinked, condylar knee prostheses that are designed to have a maximum active flexion of 155 degrees. The GSF designation indicates that the design of the femoral component has been modified slightly to address specific anatomic features of the distal femur that can be seen in both male and female patients, but are more typical of a female patient.
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.

Specific uses with CR-Flex GSF or LPS-Flex GSF femorals: Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. The CR-Flex GSF femoral, when used with 90-prefix *NexGen* CR articular surfaces, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm *Prolong*™ Highly Crosslinked Polyethylene CR articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees. The LPS-Flex GSF femoral, when used with LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

Comparison to Predicate Device:

Except for modifications to address specific anatomic features typical of a female patient, these components are identical to their respective predicate device. The device is packaged and sterilized using the same materials and processes.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing and Finite Element Analysis of the *NexGen* Knee GSF Femoral Components indicate that they are substantially equivalent to the predicate devices.

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

APR 20 2006

Zimmer, Inc.
c/o Mr. Stephen McKelvey, MA, RAC
Manager, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K060370
Trade/Device Name: *NexGen*® Knee Gender Solutions Female (GSF) Femoral Components
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: February 10, 2006
Received: February 13, 2006

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.

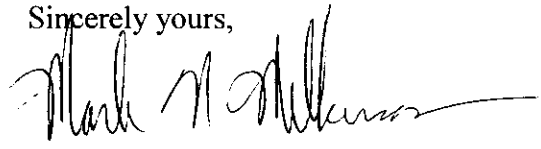
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

K060370

Indications for Use

510(k) Number (if known):

Device Name:

NexGen® Knee Gender Solutions Female (GSF) Femoral 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.

This device is intended for cemented use only.

Specific uses with CR-Flex GSF or LPS-Flex GSF femorals:
- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The CR-Flex GSF femoral, when used with 90-prefix *NexGen* CR articular surfaces, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm *Prolong*™ Highly Crosslinked Polyethylene CR articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
- The LPS-Flex GSF femoral, when used with LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ~~X~~ No (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, Restorati
and Neurological Devices

510(k) Number K060370