

Summary of Safety and Effectiveness

JUL - 6 2007

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
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Date: April 18, 2007

Trade Name: *Gender Solutions™ Natural-Knee® Flex System;*
NexGen® Complete Knee Solution CR-Flex Gender
Solutions Female (GSF) Femoral Component

Common Name: Total Knee Prosthesis

Classification Name and Reference: Knee joint patellofemorotibial
polymer/metal/polymer semiconstrained cemented
prosthesis
21 CFR § 888.3560

Knee joint patellofemorotibial metal/polymer
porous-coated uncemented prosthesis
21 CFR § 888.3565

Predicate Devices: *Gender Solutions Natural-Knee Flex System,*
manufactured by Zimmer, Inc., K070214, cleared
March 16, 2007.
NexGen Knee Gender Solutions Female (GSF)
Femoral Components, manufactured by Zimmer,
Inc., K060370, cleared April 28, 2006.

Device Description: The *Gender Solutions Natural-Knee Flex (N-K Flex)* and *NexGen CR-Flex GSF* components are semiconstrained, nonlinked condylar knee prosthesis that are designed to have a maximum active flexion of 155 degrees. The GSM and GSF femoral component designations indicate that the design of the femoral components has been modified to address specific anatomical features of

the distal femur that can be seen in patients of either gender, but are more typical of male and female patients, respectively.

Intended Use:

N-K Flex System:

- Components with *CSTi* porous coating are indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).
- Components without *CSTi* porous coating are indicated for cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments with conditions of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD), correctable varus-valgus deformity and moderate flexion contracture, or failed previous surgery where pain, deformity or dysfunction persists.
- The N-K Flex femoral provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. When used with N-K Flex, *NexGen Trabecular Metal™* CR Monoblock, 90-prefix *NexGen* CR, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm *Prolong™* Highly Crosslinked Polyethylene CR articular surfaces, it is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

***NexGen* CR-Flex GSF Femoral Components:**

- 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 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, or with Gender Solutions™ Natural-Knee® Flex Congruent 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.

Comparison to Predicate Device:

Except for changes in component compatibility, the subject components are identical to the predicate device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing of the subject devices demonstrates that they are substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2007

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

Re: K071107

Trade/Device Name: Gender Solutions™ Natural-Knee® Flex System; NexGen®
Complete Knee Solution CR-Flex Gender Solutions™ Female (GSF) Femoral Component
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer
porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: MBH, JWH
Dated: June 1, 2007
Received: June 4, 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.

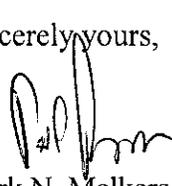
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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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 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,



Handwritten notes: mo, Dep, 3/3/07, + Reimbursement, D. R. + Reimbursement, D. R. + Reimbursement

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

Enclosure

K071107

Indications for Use

510(k) Number (if known):

Device Name:

Gender Solutions™ Natural-Knee® Flex System;
NexGen® Complete Knee Solution CR-Flex *Gender Solutions™* Femoral Component

Indications for Use:

Gender Solutions™ Natural-Knee® Flex System:

- Components with *CSTi* porous coating are indicated for uncemented or cemented use in skeletally mature individuals with intact medial and lateral collateral ligaments undergoing primary surgery for rehabilitating knees damaged as a result of Noninflammatory Degenerative Joint Disease (NIDJD) or Inflammatory Joint Disease (IJD).
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NexGen® Complete Knee Solution CR-Flex *Gender Solutions™* Femoral Component:

- This device is indicated for patients with severe knee pain and disability due to:
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- Specific uses with CR-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, or with *Gender Solutions™ Natural-Knee®* Flex Congruent 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.

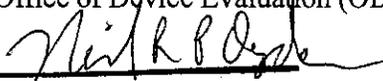
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

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