MAR 16 2007

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:	January 22, 2007
Trade Name:	*Gender Solutions*™ *Natural-Knee*® Flex System
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:	*NexGen*® Complete Knee Solution Knee *Gender Solutions* Female (GSF) Femoral Components, manufactured by Zimmer, Inc., K060370, cleared April 28, 2006. *Natural-Knee* II System with *Cancellous-Structured Titanium*™ (*CSTi*™) Porous Coating, manufactured by Zimmer, Inc., P940002, approved March 21, 1997 and reclassified to Class II February 3, 2003. *Prolong*™ Highly Crosslinked Polyethylene Cruciate Retaining Articular Surface Component, manufactured by Zimmer, Inc., K013991, cleared December 27, 2001.
Device Description:	The *Gender Solutions Natural-Knee* Flex System is a semiconstrained, nonlinked condylar knee

prosthesis that is designed to have a maximum active flexion of 155 degrees. The system includes GSM and GSF femoral components; these 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:

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 articular surfaces, it is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

Comparison to Predicate Device:

Except for minor geometrical and material modifications, the proposed components are identical to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing and Finite Element Analysis of the proposed device demonstrates that it is 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

MAR 16 2007

Zimmer, Inc.
% Brandon Hipsher, RAC
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K070214
Trade/Device Name: Gender Solutions Natural-Knee Flex System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: March 8, 2007
Received: March 9, 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchner
for

Mark N. Melkerson
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): K070214

Device Name:

Gender Solutions™ *Natural-Knee*® Flex System

Indications for Use:

- 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 articular surfaces, it is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

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

510(k) Number K070214