Summary of Safety and Effectiveness

OCT 13 2006

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Anthony Francalancia Senior Associate, Regulatory Affairs Telephone: (574) 372-4570 Fax: (574) 372-4605
Date:	September 14, 2006
Trade Name:	*NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS)-Flex Fixed Bearing *Tivanium*® Ti-6Al-4V Alloy Femoral Components
Common Name:	LPS-Flex Fixed Bearing Tivanium Femoral Components
Classification Name:	Knee joint patellofemorotibial polyethylene/metal/polyethylene semiconstrained cemented total knee prosthesis
Classification Reference:	21 CFR § 888.3560
Predicate Device:	*NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS)-Flex Fixed Bearing Femoral and Articular Surface Components, manufactured by Zimmer, Inc., K991581, cleared July 30, 1999
Device Description:	The LPS-Flex Fixed Bearing Knee is a semiconstrained, condylar system for use without the cruciate ligaments when additional stability is required to prevent anterior subluxation of the femur relative to the tibia in flexion.
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.

Specific uses with LPS-Flex femorals:

- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The LPS-Flex femoral, when used with the 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 a change in material and surface hardening processing, the LPS-Flex Fixed Bearing Tivanium Femoral Components are identical to the predicate device's femoral components. 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 (Non-clinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (laboratory) performance testing demonstrate that the 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
% Mr. Anthony Francalancia
Senior Associate, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

OCT 13 2006

Re: K062768
Trade/Device Name: *NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS)-Flex Fixed Bearing *Tivanium*® Ti-6Al-4V Alloy 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: September 14, 2006
Received: September 15, 2006

Dear Mr. Francalancia:

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,

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): K062768

Device Name:

NexGen® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS)-Flex Fixed Bearing *Tivanium*® Ti-6Al-4V Alloy 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.
- Specific uses with LPS-Flex femorals:
  - Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
  - The LPS-Flex femoral, when used with the 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_ 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 K062768