JUL 30

K991581

zimmer

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510(k) Summary of Safety and Effectiveness
***NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS);**
LPS-Flex Fixed Bearing Femoral and Articular Surface Components

I. Submitted by:

Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

II. Contact Person:

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Regulatory Affairs
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III. Date Prepared:

May 6, 1999

IV. Name of Device:

A.	Trade Name:	Femoral and Articular Surface Knee Components
B.	Proprietary Name:	*NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components
C.	Common Name:	LPS-Flex Fixed Bearing Knee
D.	Classification Name and Reference:	Knee joint patellofemorotibial polyethylene/metal/polyethylene semiconstrained cemented total knee prosthesis – 21 CFR 888.3560

E. Predicate Device:

NexGen® Complete Knee Solution *Legacy*® LPS Knee

F. 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. The LPS-Flex Fixed Bearing Knee consists of an LPS-Flex femoral and an LPS-Flex articular surface.

G. Intended Use:

This device is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The LPS-Flex Fixed Bearing Knee provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range. This device is intended for cemented use only.

H. Comparison to Predicate Device:

See attached table.

I. Non-clinical Performance and Conclusions:

1. The level of constraint for the proposed device was analyzed per ASTM F1223. The femoral-to-articular surface motion is resisted by the articulating surface geometry, the polyethylene spine and the close conformity between the two components. The simulation exhibited negligible displacement variances between the LPS-Flex and the predicate device. Constraint was not significantly different.

2. The contact area was also determined and showed an increase in conformity for the device as compared to the predicate.

3. The tibial baseplate interlock mechanism for the device is the same as the predicate device. A screw is added to some LPS-Flex articular surfaces to enhance fixation during high flexion.

4. No additional fatigue strength data was needed because the device uses the predicate tibial baseplate.

J. Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Technological Comparison to Predicate Device

Parameter	Identical, Similar or Different?	Similarities and Differences
Design	Similar	• Frontal plane conformity between the femoral and articular surface components is identical. The LPS-Flex femoral has a modified sagittal plane as compared to the predicate. This gives the LPS-Flex increased conformity during walking gait angles of flexion and accommodates the extended flexion range. • Compatibility between predicate and LPS-Flex components is high (predicate femorals can be used with the LPS-Flex articular surface). • The patellar groove design is identical for the predicate and LPS-Flex device. The same patella is used for both devices. • One additional posterior femoral bone cut is required to accommodate the extended flexion range of the LPS-Flex, otherwise the box and patellar groove geometries are the same as the predicate and standard *NexGen* instrumentation may be used. • To improve stability of the femoral component on the articular surface and to reduce the moment applied to the polyethylene spine, the shape of the femoral cam was modified and the clearance posterior to the polyethylene spine was deepened. This improves resistance to subluxation beyond the predicate and provides for the correct rollback and kinematics of the LPS-Flex joint. The cam and spine geometries of the LPS-Flex were also designed to provide a low cam/spine contact which reduces the bending load on the spine during high load flexion activities, such as squatting.
Materials	Similar	• Femoral component is *Zimaloy*® Cobalt-Chromium-Molybdenum Alloy for both the predicate and LPS-Flex. • Articular surface is UHMWPE for both the predicate and LPS-Flex. A *Tivanium insert* is added to the LPS-Flex. • Surface characteristics are identical for both the predicate and LPS-Flex (Uncoated, PMMA coated and *Conidium* hardened).
Performance	Similar	• Interlock mechanism – 17 and 20 mm thick LPS-Flex articular surfaces require a secondary screw fixation, in addition to the dovetail locking system already present in the predicate and LPS-Flex. This screw provides an additional safety factor to prevent anterior lift-off of the articular surface from the tibial baseplate. • Tibial Baseplate Fatigue Strength – The LPS-Flex knee uses the predicate tibial baseplate and has the same fatigue strength. • Lateral Stability of the Patellofemoral Joint – The patellar groove design and stability of the LPS-Flex femoral component is the same as the predicate. Both are used with all-polyethylene patellar components. • Wear Data –The LPS-Flex has a minimum polyethylene thickness of 6.5 mm. Even though the LPS-Flex increases the maximum active flexion angle to 155 degrees, the design has maintained the conformity necessary to minimize or eliminate any new movement mechanisms that could affect wear.

Parameter	Identical, Similar or Different?	Similarities and Differences
Sterility	Identical	• There are no differences between the predicate and LPS-Flex sterility processes. Both are terminally sterilized by gamma radiation. Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. The products are accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better (ANSI/AAMI/ISO 11137-1994, ANSI/AAMI ST32-1991 and ISO/TR 13409-1996).
Biocompatibility	Identical	• Material specifications for both the predicate and LPS-Flex meet or exceed ASTM standards, are common to orthopaedic products today and do not require additional biocompatibility testing.
Pyrogenicity	Identical	• Neither the predicate or the LPS-Flex are labeled as nonpyrogenic. Per USP XXIII, NF18 (1995 edition), page 1719, "These requirements do not apply to orthopaedic products."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Mr. Steven H. McKelvey
Senior Regulatory Affairs Associate
Zimmer Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K991581
Trade Name: NexGen Complete Knee Solution Legacy Posterior Stabilized (LPS)- Flex Fixed Bearing Femoral and Articular Surface Components
Regulatory Class: II
Product Code: JWH
Dated: May 6, 1999
Received: May 7, 1999

Dear Mr. McKelvey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Page ____ of ____

510(k) Number (if known): K 991581

Device Name:

NexGen® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components

Indications for Use:

This device is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The LPS-Flex Fixed Bearing Knee 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 LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees. This device is intended for cemented use only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991581

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use ____
(Optional Format 1-2-96)