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Summary of Safety and Effectiveness

Submitter:

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

Contact Person:

Stephen McKelvey
Manager, Regulatory Affairs
Telephone: (219) 372-4944
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Date:

October 11, 2001

Trade Name:

NexGen® Complete Knee Solution Rotating Hinge Knee

Common Name:

Total Knee Prosthesis

Classification Name and Reference:

Knee joint femorotibial metal/polymer constrained cemented prosthesis, 21 CFR § 888.3510

Predicate Device:

Finn Knee System, manufactured by Biomet, K945028, cleared February 14, 1996

Device Description:

The *NexGen* Rotating Hinge Knee (RHK) is a knee prosthesis that is constrained in the anterior/ posterior and medial/lateral directions but allows flexion/extension and rotation between the femoral and tibial components. Constraint in the anterior/ posterior and medial/lateral directions is accomplished by means of a femoral hinge post extension inserted through the polyethylene articular surface into the tibial baseplate.

This prosthesis is designed to be used with Zimmer *NexGen*® Complete Knee Solution patellar components, femoral and tibial augments, and stem extensions. The articular surface is available in multiple thicknesses to facilitate soft tissue tensioning and joint line restoration. Tibial baseplate components are available in multiple sizes to allow for optimal bone coverage and surgical options.

Intended Use:

This device is indicated for moderate to severe knee instability, significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle, valgus, varus, or flexion deformities and/or for the salvage of previously failed surgical attempts. This device is intended for cemented use only.

Comparison to Predicate Device:

The RHK device is substantially equivalent to the Finn Knee System in that both have similar indications, design (both are constrained, rotating hinge knee prostheses), materials and mechanical safety. Both devices are intended for cemented use only.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Constraint testing is not applicable to a constrained prosthesis. This test was not necessary.

Contact area was greater for the RHK than the Finn for the range 0 - 120°. At 130°, the Finn had greater contact area.

The RHK interlock mechanism passed all distraction (lift-off) testing.

All RHK test samples completed the 10 million cycle Tibial Baseplate Fatigue Strength testing without evidence of fracture or cracking.

No additional lateral stability of the patellofemoral joint data was needed because the RHK uses similar patella femoral tracking as previously cleared *NexGen* femoral components.

No additional shear strength or metal-backed patella static tensile data was needed because the RHK uses previously cleared patella devices.

The RHK components passed all combined load fatigue and pin loosening testing.

Minimum polyethylene thickness is greater than 6 mm, therefore, wear testing was not needed for the RHK 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

JAN 0 9 2002

Mr. Stephen McKelvey
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K013385
Trade/Device Name: *NexGen* Complete Knee Solution Rotating Hinge Knee
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: October 11, 2001
Received: October 12, 2001

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
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): K013385

Device Name:

NexGen® Complete Knee Solution Rotating Hinge Knee

Indications for Use:

This device is indicated for moderate to severe knee instability, significant bone loss and/or ligament deficiencies caused by neoplasms, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle, valgus, varus, or flexion deformities and/or for the salvage of previously failed surgical attempts

This device is intended for cemented use only.

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K013385

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)