K013991

DEC 2 7 2001

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, Indiana 46581-0708 (219) 267-6131
Contact Person:	Stephen McKelvey Manager, Regulatory Affairs
Telephone: Fax:	(219) 372-4944 (219) 372-4605
Date:	December 20, 2001
Trade Name:	*Prolong*™ Highly Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Component
Common Name:	Crosslinked Articular Surfaces
Classification Name and Reference	Knee joint patellofemorotibial polyethylene/ metal/ polyethylene semiconstrained cemented total knee prosthesis – 21 CFR 888.3560
Predicate Devices:	The predicate device for the *Prolong* CR Articular Surface Component is the *NexGen*® Complete Knee Solution Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Component, K003910, cleared March 19, 2001.
Device Description:	These components are manufactured of machined Ultra-High Molecular-Weight (UHMWPE) polyethylene. Both the modified and predicate devices are crosslinked by exposure to electron-beam (e-beam) radiation.

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. This device is intended to be used as part of a cemented knee system.
Comparison to Predicate Devices:	Except for a minor modification to the patellar cutout, *Prolong* Highly Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Components are identical to the predicate device. The modification does not change the intended use or the fundamental scientific technology. It is packaged and sterilized using the same materials and processes.
Performance Data:	Performance testing completed as part of the design assurance procedure demonstrated that this device is safe and effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2001

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

Re: K013991
Trade/Device Name: *Prolong*™ Highy Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Component
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: December 3, 2001
Received: December 4, 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.

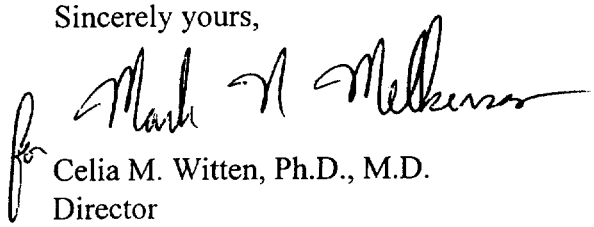
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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): K013991

Device Name:

Prolong™ Highly Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Component

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.

Prolong crosslinked polyethylene cruciate retaining articular surfaces are intended to be used as part of a cemented knee system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhern
(Division Sign-Off)
Division of Cardiovascular
and Neurological Devices

510(k) Number K013991