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Summary of Safety and Effectiveness

MAR 0 4 2003

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dalene T. Binkley, RAC Associate, Regulatory Affairs Telephone: (574) 372-4907 Fax: (574) 372-4605
Date:	January 21, 2003
Trade Name:	*CPT*® 12/14 Hip Prostheses
Common Name:	Total hip prosthesis
Classification Name and Reference:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented 21 CFR § 888.3350
Predicate Device:	Collarless Polished Taper and Collarless Polished Taper LS Hip Prostheses, manufactured by Zimmer, K960658, cleared July 16, 1996.
Device Description:	The *CPT*® 12/14, like its predicate, is a one-piece straight, collarless and highly polished femoral stem that is intended to be used for cemented fixation into the intramedullary canal for pathological or degenerative conditions involving the femur and/or acetabulum
Intended Use:	The *CPT*® 12/14 Hip Prostheses are indicated for use with patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur and in the presence of proximal femoral bone defects; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous

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	fusion; patients with previously failed endoprostheses and/or total hip components in the affected extremity; and patients with acute femoral neck fractures.
Comparison to Predicate Device:	The modifications to the Collarless Polished Taper and Collarless Polished Taper LS Hip Prostheses change neither the intended use nor the fundamental scientific technology of the device. It is packaged and sterilized using the same materials and processes. The modified device was created to offer a line extension to provide the surgeon with more options.
Performance Data:	Non-clinical performance testing demonstrated that the modified devices are equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Ms. Dalene T. Binkley
Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K030265
Trade/Device Name: CPT 12/14 Hip Prostheses
Regulation Numbers: 21 CFR 888.3350
Regulation Names: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: February 18, 2003
Received: February 19, 2003

Dear Ms. Binkley:

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 (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 Mark N. Melkerson

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): K030265

Device Name:

CPT® 12/14 Hip Prosthesis

Indications for Use:

The *CPT*® 12/14 Hip Prostheses are indicated for use with patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur and in the presence of proximal femoral bone defects; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the affected extremity; and patients with acute femoral neck fractures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

Division Sign-Off

Division of Cere[illegible]ative

and Neurolo[illegible]

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Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)