SEP 5 2002

K021891
page 1 of 2

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Fred McClure Senior Associate, Regulatory Affairs Telephone: (574) 372-4294 Fax: (574) 372-4605
Date:	June 6, 2002
Trade Name:	*Zimmer* Trabecular Metal Modular Acetabular System
Common Name:	Acetabular component for total Hip prosthesis
Classification Name and Reference:	Hip joint metal/polymer semi-constrained cemented prosthesis; 21 CFR § 888.3350 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; 21 CFR § 888.3358
Predicate Device:	*Trilogy*® Acetabular System, manufactured by Zimmer, Inc., (K934765), cleared April 29, 1994; and Implex Hedrocel Modular Elliptical Acetabular Cup, manufactured by Implex Corp., (K001039), cleared June 15, 2000.
Device Description:	The *Zimmer* Trabecular Metal Modular Acetabular System is a modular acetabular cup system intended to replace a hip joint and designed to achieve fixation to bone either with or without the use of bone cement. The system consists of a shell and liner. The shell substrate is made from *Tivanium*® Ti-6Al-4V Alloy. The outer porous material, which is metallurgically bonded to the shell substrate, is made of Trabecular Metal. The Trabecular Metal material has an elliptical outer diameter and a hemispherical inner diameter to allow hemisphere to hemisphere bonding between the Trabecular Metal and the *Tivanium* substrate.

K041891
page 2 of 2

Three porous acetabular shell designs are available: one with screw holes, one with cluster screw holes and one without screw holes. The shells range in diameter from 38 to 80 mm in 2mm increments. The screw holes permit the use of *Tivanium* Alloy screws to provide immediate fixation and security. Screws are available in 4.5 and 6.5mm diameters with varying lengths. The shell incorporates a threaded polar hole to attach the cup positioner.

Intended Use:

This device is indicated for primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis and diastrophic variant.
This device is intended for either cemented or noncemented use.

Comparison to Predicate Device:

The *Zimmer* Trabecular Metal Modular Acetabular System incorporates the same materials, has the same intended use, and similar technological and geometrical features as the legally marketed predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The Trabecular Metal/*Tivanium* alloy interface was tested per applicable FDA Guidance Documents and ASTM Standards and the results demonstrated that the interface will maintain its integrity under physiological loads.

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

SEP 5 2002

Mr. Fred McClure
Senior Associate, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K021891
Trade Name: Zimmer Trabecular Metal Modualr Acetabular System
Regulation Number: 21 CFR 888.3350 and 888.3358
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JDI and LPH
Dated: June 6, 2002
Received: June 7, 2002

Dear Mr. McClure:

We have reviewed your Section 510(k) premarket 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) 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.

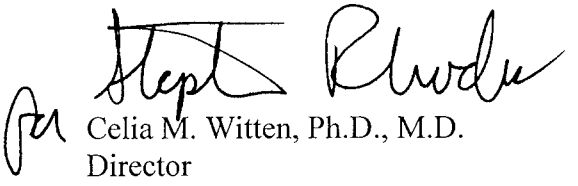
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K021891

Device Name:

Zimmer® Trabecular Metal Modular Acetabular System

Indications for Use:

This device is indicated for primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis and diastrophic variant.

This device is intended for either cemented or noncemented use.

(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 K021891

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