1 of 2

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Karen Cain Manager, Corporate Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	June 7, 2005
Trade Name:	*Trabecular Metal*™ Revision Shell Liners
Common Name:	Acetabular Cup
Classification Name and Reference:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented 21 CFR § 888.3350
Predicate Device:	Implex Hedrocel® Replacement Cup Insert, manufactured by Zimmer TMT (formerly known as Implex), K983128, cleared December 3, 1998.
Device Description:	This modified device is intended for cemented use in conjunction with a *Trabecular Metal* Revision Shell. The liner is offered in a broad range of sizes with 0- and 10-degree face angle versions to accommodate a variety of patient anatomies.
Intended Use:	The *Trabecular Metal* Revision Shell Liners are indicated for cemented use in the *Trabecular Metal* Revision Shell for initial placement or as an in situ replacement polyethylene bearing surface for joint instability, wear and/or damage.
Comparison to Predicate Device:	Except for a change in material and minor dimensional changes, the *Trabecular Metal* Revision Shell Liners are identical to the predicate device. The modified device uses the same operating principle, intended uses and fixation method as the predicate device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing demonstrated that the *Trabecular Metal* Revision Shell Liners are substantially equivalent to the predicate 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

JUL 27 2005

Ms. Karen Cain
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K051516
Trade/Device Name: Trabecular Metal™ Revision Shell Liners
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: July 14, 2005
Received: July 15, 2005

Dear Ms. Cain:

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.

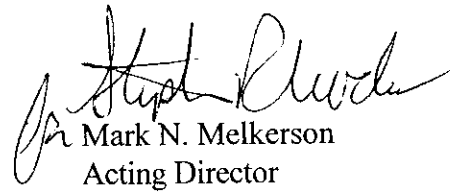
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051516/S1

Indications for Use

510(k) Number (if known):

Device Name:

Trabecular Metal™ Revision Shell Liners

Indications for Use:

The *Trabecular Metal* Revision Shell Liner is indicated for cemented use in the *Trabecular Metal* Revision Shell for initial placement or as an in situ replacement polyethylene bearing surface for joint instability, wear and/or damage.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K051516