K072121

**Summary of Safety and Effectiveness**

JAN - 7 2008

| | |
|---|---|
| **Submitter:** | Zimmer, Inc.<br>P.O. Box 708<br>Warsaw, IN 46581-0708 |
| **Contact Person:** | Patricia Jenks<br>Specialist, Corporate Regulatory Affairs<br>Telephone: (574) 371-8354<br>Fax: (574) 372-4605 |
| **Date:** | October 11, 2007 |
| **Trade Name:** | *Trabecular Metal*™ Acetabular Revision System Cemented Constrained Liner |
| **Common Name:** | Constrained Acetabular Liner |
| **Classification Names and References:** | 21 CFR 888.3310: Hip joint metal / polymer constrained cemented or uncemented prosthesis, Product code: 87 KWZ |
| **Predicate Device:** | *Trilogy*® *Longevity*® Constrained Liner, K071718, cleared July 13, 2007 and *Trabecular Metal* Revision Shell Liners, K051516, cleared July 27, 2005. |
| **Device Description:** | The *Trabecular Metal* Acetabular Revision System Cemented Constrained Liner is a polyethylene/metal acetabular liner, which, when used with a *Trabecular Metal* Acetabular Revision Shell (K050937, cleared May 11, 2005), forms the acetabular component of a total hip prosthesis. The device consists of a *Longevity* highly crosslinked polyethylene liner and a *Tivanium*® Titanium alloy constraining ring.<br><br>The liner allows for mechanical capture of the metal femoral head and greater flexion/extension range of motion than hooded constrained liner designs. |

| | |
|---|---|
| | Subject acetabular liners are available in inner diameters of 28, 32 and 36mm. |
| **Intended Use:** | The *Trabecular Metal* Acetabular Revision System (TMARS) Cemented Constrained Liner is intended to be cemented into a TMARS shell; the shell is intended for cementless fixation into the acetabulum. The *Trabecular Metal* Acetabular Revision System Cemented Constrained Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered. |
| **Comparison to Predicate Device:** | Two predicates form the design of the *Trabecular Metal* Acetabular Revision System Cemented Constrained Liner. The front side/femoral head capture region exactly matches the *Trilogy Longevity* Constrained Liner and the backside has been modified with cement interdigitation grooves to allow for cement fixation into a *Trabecular Metal* Acetabular Revision Shell, exactly matching the backside of the *Trabecular Metal* Revision Shell Liners. |
| **Performance Data (Nonclinical and/or Clinical):** | Non-Clinical Performance and Conclusions:<br><br>Mechanical Testing of the modified device indicates that it is substantially equivalent to the predicate.<br><br>Clinical Performance and Conclusions:<br><br>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 - 7 2008

Zimmer, Inc.
c/o Ms. Patricia Jenks
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, IN 46581-0708

Re: K072121
Trade/Device Name: *Trabecular Metal*™ Acetabular Revision System
Cemented Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained
cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWZ
Dated: December 20, 2007
Received: December 26, 2007

Dear Ms. Jenks:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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):** K072121

**Device Name:**

*Trabecular Metal*™ Acetabular Revision System Cemented Constrained Liner

**Indications for Use:**

The *Trabecular Metal* Acetabular Revision System (TMARS) Cemented Constrained Liner is intended to be cemented into a TMARS shell; the shell is intended for cementless fixation into the acetabulum. The *Trabecular Metal* Acetabular Revision System Cemented Constrained Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intraoperative instability and for whom all other options to constrained acetabular components have been considered.

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)

FOR M. MELKERSON

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

**510(k) Number** K072121