K050937
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Trabecular Metal Acetabular Revision Shells

Submitter Name: Zimmer Trabecular Metal Technology, Inc.

Submitter Address: 80 Commerce Drive
Allendale, New Jersey 07401-1600

Contact Person: Marci Halevi

Phone Number: (201) 818-1800 ext. 507

Fax Number: (973) 879-0825

Date Prepared: April 11, 2005

Device Trade Name: The Trabecular Metal Acetabular Revision Shell

Device Common Name: Acetabular revision shells or cages

Classification Number: 21 CFR § 888.3358 and 21 CFR § 888.3350

Substantial Equivalence: **The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.**

Device Description: The Trabecular Metal Acetabular Revision Shell is a modular acetabular reconstructive device (polyethylene liner is cemented to shell) intended for use in primary or revision reconstructive procedures of the acetabulum. The subject Trabecular Metal Acetabular Revision Shell is manufactured from Trabecular Metal porous tantalum. The TM Revision Shell has a Ti-6A1-4V instrument interface ring (ASTM F-136) along its outer perimeter that provides a rigid contact area for the impaction instrument used to implant the device. The Revision Shells are intended for either cementless or cemented fixation to the acetabulum with that allow for optional ancillary fixation to the acetebulum. The screwholes mate with commercially available Zimmer 6.5mm titanium alloy bone screws.

510(k) Summary (Continued)

Indications for Use: The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

- For cemented or cementless use.
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problem where arthrodesis or alternative reconstruction techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Conclusion: The Trabecular Metal Acetabular Revision Shells are substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Ms. Marci Halevi
Manager of Regulatory Affairs
Zimmer Trabecular Metal Technology
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K050937
Trade/Device Name: Trabecular Metal Acetabular Revision Shells
Regulation Number: 21 CFR 888.3358, 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI
Dated: April 11, 2005
Received: April 14, 2005

Dear Ms. Halevi:

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 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/industry/support/index.html

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050937

Device Name: Trabecular Metal Acetabular Revision Shells

Indications For Use:

The Indications for Use of the Trabecular Metal Acetabular Revision Shells are:

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  Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use (Per 21 CFR 801 Subpart D) Yes AND/OR... Over-The-Counter Use No

(21 CFR 801 Subpart C)
(Optional Format 09-2004)

(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 K050937