MAY 26 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Explant™ Osteonecrosis Intervention Implant Removal Kit

Submitter Name	Zimmer Trabecular Metal Technology, Inc.
And Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	May 4, 2005
Device Trade Name:	The **Explant™ Osteonecrosis Intervention Implant Removal Kit**
Device Common Name:	Explant Instruments
Classification Number and Name:	**21CFR878.4820 General and Plastic Surgery Devices**

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 instruments are supplied sterile in a preassembled kit. Two size kits are available; a 10mm ID kit and a 14mm ID kit. The 10mm kit cannot be used alone and must be used in combination with the 14mm kit. The instrument come preassembled to Zimmer Hudson Fitting Adaptors, allowing the Tubes to be driven via a Zimmer T-Handle or a Zimmer Power Driver. The Hudson fittings can be removed to expose a through-hole at the end of the tube to allow for removal of a specimen that remains in the coring tube. All components of these kits are single use only.

Indications for Use:

The ***Explant™ Osteonecrosis Intervention Implant Removal Kit*** is intended for removal of a Trabecular Metal™ Osteonecrosis Intervention Implant.

Device Technological Characteristics and Comparison to Predicate Device:

A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Conclusion:

The ***Explant™ Osteonecrosis Intervention Implant Removal Kit*** is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

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

Re: K050766
Trade/Device Name: Explant® Osteonecrosis Intervention Implant Removal
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachments
Regulatory Class: I
Product Code: HWE
Dated: March 23, 2005
Received: March 25, 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) 276-0115 . 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): **K050766**

Device Name: **Explant® Osteonecrosis Intervention Implant Removal Kit**

Indications For Use: **The Explant® Osteonecrosis Intervention Implant Removal Kit is intended for removal of a Trabecular Metal™ Osteonecrosis Intervention Implant.**

Prescription Use __√__ 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 K050766