

SEP 30 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**Trabecular Metal Femoral Cone Augments**

Submitter Name And Address: Implex Corp.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Contact Person: Marci Halevi

Phone Number: (201) 818-1800

Fax Number: (973) 829-0825

Date Prepared: March 5, 2004

Device Trade Name: Trabecular Metal Femoral Cone Augments

Device Common Name: Knee System Augments

Classification Number and Name: 21 CFR § 888.3560 Prosthesis, Knee

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 Femoral Cone Augments are to be used in conjunction with Zimmer Inc.'s LCCK and Rotating Hinge Knee femoral components. The subject devices are used to address distal femoral cavitory defects encountered when implanting either of these two systems. The design of the augment interface inversely corresponds to the design of an LCCK or Rotating Hinge Knee femoral component. The augment has a rectangular, tapered shape. The opposing sides of the rectangle are longer than the center allowing the sides of the augment to fit into the condyles of the femoral component and the center of the augment to fit over the "box" of the femoral component. The center of the augment is hollow to allow passage of the stem through the center of the cone and into the femoral canal. The augments are fixed to the femoral component with bone cement. The Trabecular Metal Femoral Cone Augments are for cemented use along the bone in the USA, and for cementless or cemented use along the bone outside the USA.

510(k) Summary (Continued)

Indications for Use:	The Trabecular Metal Femoral Cone Augments are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. The Trabecular Metal Tibial Cone Augments are for cemented use only in the USA, and for cementless or cemented use outside the USA.
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.
Performance Data:	Testing of the subject devices were not performed. Previous testing of Trabecular Metal and Trabecular Metal devices support a determination of substantial equivalence.
Conclusion:	The Trabecular Metal Femoral Cone Augments are 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

SEP 3 0 2004

Marci Halevi
Manager of Regulatory Affairs
Implex Corp
80 Commerce Drive
Allendale, New Jersey 07401

Re: K040630

Trade/Device Name: Trabecular Metal Femoral Cone Augments

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/ metal/polymer semi-constrained
cemented prosthesis

Regulatory Class: II

Product Code: JWH

Dated: July 1, 2004

Received: July 2, 2004

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

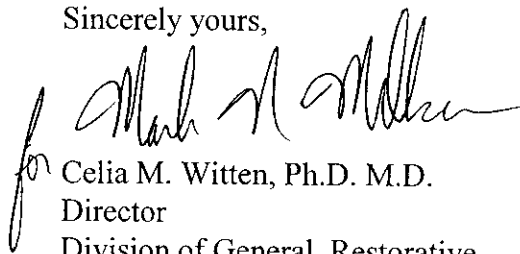
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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) 276-4659. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D. M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

1 of 1

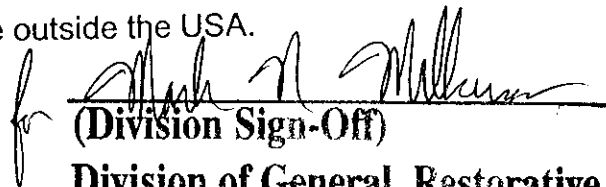
510(k) Number (if
known):K040630

Device Name:

Trabecular Metal Femoral Cone Augments

Indications For Use:

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(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K040630

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR...

Over-The-
Counter Use ☐

(Optional Format 1-2-96)