K031399

510(k) SUMMARY

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitted By: Interpore Cross International
181 Technology Drive
Irvine, California 92618

Date: December 16, 2003

Contact Person: Mark Loar
Manager, Regulatory and Clinical Affairs

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Human Tissue
Common/Usual Name: DBM Bone Graft Substitute
Product Classification: Unclassified
Proprietary Name: InterGro® DBM

PREDICATE DEVICE

Predicate device information is provided in this premarket notification.

DEVICE DESCRIPTION

InterGro® DBM products contain human tissue (allograft bone) and are intended for transplantation. The allograft bone has been granulated, demineralized and provided in a lipid carrier. Some versions contain porous ceramic granules that are a composite of highly resorbable calcium carbonate with a slower resorbing 2 to 10 um outer layer of calcium phosphate.

InterGro DBM products have been processed aseptically and are ready to use. They do not require rehydration or any special preparation. InterGro DBM is intended for single patient use only.

INDICATIONS-FOR-USE

InterGro DBM products are to be used for filling bony voids or gaps in the extremities, and pelvis that are not intrinsic to the bony stability of the structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. The device may also be used for filling craniofacial defects and craniotomies that are no larger than $25cm^2$. The amount of InterGro DBM products to be used should be based on the type of procedure and size of the graft site.

SUBSTANTIAL EQUIVALENCE INFORMATION

InterGro® DBM was found to be substantially equivalent to the predicate devices. The safety and effectiveness of InterGro DBM is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

- Viral Inactivation Validation
  The methods for processing the DBM contained in InterGro® DBM were evaluated for their viral inactivation potential. A select panel of viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing methods for a wide range of potential human viruses.

- Osteoinductive Potential
  Each lot of DBM incorporated into InterGro® DBM is assayed for its osteoinductive potential. The assay measures the proliferation of SAOS human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductive index). Results of the assay have been correlated with results from implantation of DBM into athymic rat muscle, which demonstrated a correlation coefficient of 0.850 ($p<0.0005$) and accurately predicted the in vivo osteoinductivity in 25 donor lots.[1] Additionally, clinical results using DBM with >0.20 and ≤0.20 (osteoinductive index) demonstrated a significant difference in healing as evaluated by radiography, 92% and 33% healing, respectively.[2]

  The combination of DBM, the carrier and, in some formulations, ceramic granules has not been evaluated for osteoinductivity; therefore it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in-vitro* "SAOS" bioassay will correlate with human clinical performance of InterGro DBM products.

  [1] Adkisson HD, Strauss-Schoenberger J, Gillis M, Wilkins R, Jackson M, and Hruska KA. Rapid Quantitiative Bioassay of Osteoinduction. J Ortho Res, 2000, 18:503-511.

  [2] Wilkins RM, Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture, Advances in Tissue Banking. 1999 3:113-124

- Product Performance Testing
  Performance of InterGro® DBM was evaluated in rabbit and sheep models by radiographic and histological methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Mr. Mark Loar
Manager, Regulatory and Clinical Affairs
INTERPORE CROSS International
181 Technology Drive
Irvine, California 92618

Re: K031399
Trade/Device Name: InterGro® DBM
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV,GXP
Dated: December 16, 2004
Received: December 21, 2004

Dear Mr. Loar:

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.

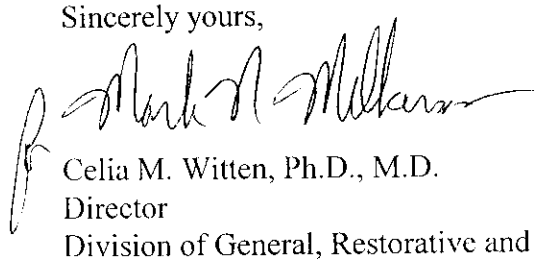
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K031399

Device Name: InterGro® DBM

Indications-For-Use:

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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 Mark A Milhous

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

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