K070147

MAY 14 2007

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	BIOMET 3i 4555 Riverside Drive Palm Beach Gardens, FL 33410
Establishment Registration Number:	1038806
Contact:	Tamara J. Nelson Regulatory Affairs Supervisor BIOMET 3i 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel. 561-776-6923 Fax. 561-514 6316 Email tnelson@3implant.com
Date Prepared:	August 29, 2006
Trade/Proprietary Name:	InterGro® Oral (Putty, Paste, Plus)
Common/Usual Name:	DBM Bone Graft Substitute
Classification Name:	Bone Grafting Material
Device Classification:	Class II
Predicate Device:	GRAFTON® DBM (Gel, Flex, Putty, Matrix, Crunch)
Device Formulation:	InterGro® DBM (Paste, Putty, Plus)
Performance:	Performance standards applicable to DBM based products have not been published by the FDA. BIOMET 3i intends to contract Interpore Cross International to manufacture and package this device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably present. Voluntary performance standards, such as materials certifications, in-house SOP's, FDA Guidance Documents, AATB Standards and/or ASTM Standards are used as appropriate.

Device Description:

InterGro® Oral is a resorbable, osteoconductive, and osteoinductive bone graft substitute that resorbs and is replaced with bone during the healing process. Its main component, demineralized cortical bone matrix (DBM), is derived from donor human tissue (allograft bone) and contains various growth factors including osteoinductive proteins. The DBM has been granulated, lyophilized and aseptically processed. In some versions of the product, calcium salt granules shall be incorporated to provide additional osteoconduction and enhanced structural strength. The carrier for InterGro® Oral is a resorbable, biocompatible, semi-viscous lipid. InterGro® Oral is provided ready-to-use in various physical consistencies. It is packaged in various sizes by volume for single patient use.

Indications for Use:

InterGro® Oral is a bone filling material indicated for dental intraosseous and oral/maxillofacial defects including: localized ridge augmentations, extraction sockets, cystic defects, sinus lifts, peri-implant defects, defects associated with root resection or apicoectomy, and periodontal defects.

Conclusion:

The safety and effectiveness of InterGro® Oral is adequately supported by the substantial equivalence information, materials data, and testing results provided within this premarket notification.
InterGro® Oral was found to be substantially equivalent to the predicate device based on the intended use, base materials, select performance properties, and use of a handling material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tamara J. Nelson
Regulatory Affairs Supervisor
BIOMET 3i
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

MAY 14 2007

Re: K070147
Trade/Device Name: InterGro® Oral
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: March 8, 2007
Received: March 12, 2007

Dear Ms. Nelson:

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.

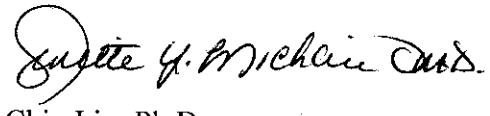
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070147

Device Name: InterGro® Oral

Indications for Use:

InterGro® Oral is a bone filling material indicated for dental intraosseous and oral/maxillofacial defects including: localized ridge augmentations, extraction sockets, cystic defects, sinus lifts, peri-implant defects, defects associated with root resection or apicoectomy, and periodontal defects.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
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