5809 Ward Court
Virginia Beach, VA 23455
Tel: 757-464-4761
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www.lifenet.org

510(k) SUMMARY
[As Required by 21 CFR 807.92(c)]

Submitter's Name & Address: LifeNet
5809 Ward Court
Virginia Beach, VA 23455

Contact Person: David Klementowski
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E-mail: david_klementowski@lifenet.org

Date Summary Prepared: October 31, 2005

Device Name: Trade/Proprietary Name – Optium DBM™ Gel
Optium DBM™ Putty
Common/Usual Name – Bone Void Filler,
Bone Graft
Substitute
Classification Name – Resorbable calcium salt
bone void filler device
(21 CFR 888.3045)

Predicate Devices – The current devices share some or all of the same characteristics- intended use, product technical characteristics and performance characteristics as described below for Allomatrix® Putty (K020895 / K041168), Osteofil® various forms (K043420) and Exactech Resorbable Bone Paste (K020078).

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Device Description:

These devices are comprised of sterile USP grade glycerol/glycerin and combined with human demineralized cortical bone at the point of manufacture.

Intended Use:

Optium DBM™ Gel and Putty are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be placed into the bony voids or gaps of the skeletal system (e.g., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products provide a bone void filler that remodels into the recipient's skeletal system.

Technological Characteristics:

Optium DBM™ Gel and Putty and one or more of its predicate devices are comprised of similar components, such as a non-tissue derived excipient to improve the handling characteristics of the demineralized bone matrix (DBM). The glycerol excipient is resorbable like the PEG excipient in the Exactech Resorbable paste (K020078). Optium DBM™ Gel and Putty and all its predicate devices contain human DBM. Optium DBM™ Gel and Putty and all of its predicate devices have the same intended use as a bone void filler. Optium DBM™ Gel and Putty and all of its its predicate devices are available culture negative/sterile and in multiple forms (gels, pastes and/or putties). The differences between Optium DBM™ Gel and Putty and their predicate devices do not raise new questions of safety or efficacy.

Non-Clinical Performance Data Supporting Substantial Equivalence Determination:

Optium DBM ™ Gel and Putty and at least one of its predicate devices were compared in an *in vivo* assay[1] for new bone formation. Results from these studies indicate that Optium DBM ™ Gel and Putty products had equal to or more new bone formation than the predicate device(s) assessed and therefore can be used as a

[1] Product was screened for osteoinductive potential in the athymic mouse assay. Findings from an animal based model are not necessarily predictive of human clinical results.

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bone void filler with equivalent or better bone formation when compared to the predicate device. New bone formation was evaluated by quantitative histomorphometric analysis of the explanted samples.

Non-clinical Tests: (The following tests were conducted.)

Genotoxicity (Ref. ISO 10993-3)
- Bacterial Mutagenicity Assay (Ames)
- *In Vivo* Mouse Micronucleus Assay
- *In Vitro* Chromosomal Aberration Induction in Human Lymphocytes

Cytotoxicity (Ref. ISO 10993-5)
- MEM Elution (Product and packaging performed according to USP)

Sensitization (Ref. ISO 10993-10)
- ISO Guinea Pig Maximization Sensitization Test (Gel and Glycerol)

Irritation (Ref. ISO 10993-10)
- ISO Intracutaneous Reactivity Test

Systemic Toxicity (Ref. ISO 10993-11)
- ISO Acute Systemic Injection Test
- ISO Subacute (28-Day) Subcutaneous Study

Hemolysis (Ref. ISO 10993-4)
- *In vitro* Hemolysis Study (Human Blood) on Extract

Clinical Safety – History of Glycerol Containing Bone Void Fillers

This type of product has been on the U.S. market since 1991. Optium DBM™ Gel and Putty have been on the U.S. Market since May 2003. The Weinberg Group has analyzed data generated from clinical trials evaluating glycerol containing bone void fillers in multiple orthopedic, spinal, and dental applications. The results show a history of such products being used safely to treat these applications. Reference Section 20 of this 510(k) submission for more details.

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Summary:

Based on the results of the non-clinical tests conducted, both the Optium DBM™ Gel and Putty have demonstrated that they are as safe, as effective, and perform as well as or better than the predicate devices noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2005

David Klementowski
Director of Regulatory Affairs
Life Net
5809 Ward Court
Virginia Beach, Virginia 23455

Re: K053098
Trade/Device Name: Optium DBM™ Gel and Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MBP, MQV
Dated: October 31, 2005
Received: November 3, 2005

Dear Mr. Klementowski:

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,

for Mark N. Melkerson
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):

Device Name: Optium DBM™ Gel and Putty

Indications For Use:

These products are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be placed into the bony voids or gaps of the skeletal system (e.g., extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products provide a bone void filler that remodels into the recipient's skeletal system.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 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 K053098