K041324

Section 12: Premarket Notification 510(k) Summary

JUL 19 2004

1. Submitter's Name / Contact Person

Kim E. Aves
Regulatory Affairs Manager
Lifecore Biomedical, Inc.
Ph: 952-368-6324

2. General Information

Trade Name	CalMatrix Calcium Sulfate Bone Graft Binder • 0.173g CalMatrix Binder – for use with 0.25cc of bone graft material • 0.345g CalMatrix Binder – for use with 0.5cc of bone graft material • 0.690g CalMatrix Binder - for use with 1.0cc of bone graft material
Common / Usual Name	Surgical Grade Calcium Sulfate (Plaster of Paris)/CMC
Classification Name	None (unclassified) No formal classification of Calcium Sulfate or Plaster of Paris has been determined. Reference FDA Publication 91-4246.
Identification of Equivalent Devices	CAPSET Calcium Sulfate Bone Graft Barrier (K955096) ALLOMATRIX® Putty (K020895)

3. Device Description

Lifecore Biomedical CalMatrix Calcium Sulfate Bone Graft Binder (CalMatrix) is a calcium sulfate material that contains resorbable surgical grade plaster of paris with approximately 10% of a pharmaceutical grade sodium carboxymethylcellulose (CMC).

The Binder is a white, free-flowing powder. Calcium sulfate (CS) hemihydrate and PHARMACEUTICAL grade sodium carboxymethylcellulose are commercially available as raw materials for use in several orthopedic and dental devices. Calcium sulfate/CMC, when used in conjunction with demineralized bone matrix (DBM), controls the particles in the bony defect where bony walls may be insufficient to stabilize the graft. It increases the graft volume, and reduces particle migration during the early healing phase. CalMatrix remains pliable after mixing which allows the clinician an extended time period to complete the bone regeneration procedure.

4. Intended Use

CalMatrix Calcium Sulfate Bone Graft Binder, when mixed with allograft or other bone graft material, may be used to treat multiple types of maxillary and mandibular osseous and periodontal defects such as:

- Intrabony/infrabony defects
- Furcation defects
- Recession defects
- Dehiscence/fenestration defects (natural teeth and prosthetic root form implants)
- Extraction socket (ridge preservation) defects
- Ridge augmentation defects
- Sinus lift defects
- Endodontic bony defects

After site preparation in the usual manner, select an appropriately sized package of CalMatrix Binder to go with the quantity of bone graft material of choice selected to treat the defect size. Combine the two dry ingredients, add the syringe liquid provided in the CalMatrix package and mix. Place the composite graft into the prepared defect site and suture the soft tissue flaps back in the usual manner or as indicated by clinical expertise. The graft material may be covered by a barrier or membrane prior to suture placement if, in the judgment of the clinician, it is indicated.

5. Technological Characteristic Comparisons

Both CalMatrix and CAPSET are composed of calcium sulfate hemihydrate, with the exception that CalMatrix also includes 10% pharmaceutical grade carboxymethylcellulose (CMC). CalMatrix and ALLOMATRIX utilize the same calcium sulfate (CS)/CMC blend, except that ALLOMATRIX is provided with human demineralized bone matrix (DBM) already mixed in. CalMatrix is to be mixed with DBM or other bone graft material by the clinician prior to application. CalMatrix is also substantially equivalent to the predicate devices in terms of mechanical characteristics, product configuration, anatomical site, safety characteristics, and sterilization.

6. Performance Data

Animal studies were conducted using calcium sulfate/ CMC and demineralized bone and as well as CS/cellulose with no DBM. All the test materials were well tolerated with no inflammatory or foreign body response in the animal models. Substantial new bone growth was shown in the filled defects at follow-up. Clinical use of this product was evaluated in animal and human studies.

7. Biocompatibility

The historical use of calcium sulfate as a bone substitute is well documented in the medical literature. Plaster of Paris (calcium sulfate hemihydrate) may be the oldest bone substitute material in continuous use. Its biocompatibility has been well established.

Sodium carboxymethylcellulose (CMC) is in widespread use in a variety of industries including foods, cosmetics, medical devices and pharmaceuticals. Recent studies have

reported no inflammatory response or other adverse effects on bone healing associated with the use of CMC.

Both calcium sulfate and CMC have been shown to be biocompatible materials that are well tolerated in the oral environment for use in guided bone regeneration.

8. Conclusion (statement of equivalence)

The data submitted in this 510(k) supports substantial equivalence of Lifecore CalMatrix to the following commercially marketed devices:

- Lifecore CAPSET Calcium Sulfate Bone Graft Barrier (K955096), Lifecore Biomedical, Inc.
- ALLOMATRIX® Putty (K020895), Wright Medical Technology, Inc.

Substantial equivalence is based on the indications for use, product design and configuration, and materials used. The intended use of CalMatrix is the same as CAPSET, and the materials used are the same as those found in ALLOMATRIX (with the exception that the human demineralized bone matrix is added prior to application). The comparative analysis demonstrates the substantial equivalence of Lifecore CalMatrix to the predicate devices in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2004

Ms. Kim E. Aves
Regulatory Affairs Manager
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318-3051

Re: K041324
Trade/Device Name: CalMatrix™ Calcium Sulfate Bone Graft Binder
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LYC
Dated: May 17, 2004
Received: May 18, 2004

Dear Ms. Aves:

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 (301) 594-4518. 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,

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): K041324

Device Name: CalMatrix™ Calcium Sulfate Bone Graft Matrix
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)

Robert S Butz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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