K042930

## Section 10: Premarket Notification 510(k) Summary

FEB 14 2005

### 1. *Submitter's Name / Contact Person*

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

### 2. *General Information*

| | |
|---|---|
| **Trade Name** | CalForma™ Calcium Sulfate Bone Graft Barrier<br>• 0.5 g CalForma™<br>• 1.0 g CalForma™ |
| **Common / Usual Name** | Surgical Grade Calcium Sulfate Hemihydrate (SGCSH) (Plaster of Paris)/ HPMC |
| **Classification Name** | None (unclassified)<br>No formal classification of Calcium Sulfate or Plaster of Paris has been determined. Reference FDA Publication 91-4246. |
| **Equivalent Device** | K943186 - CAPSET® Calcium Sulfate Bone Graft Barrier |

### 3. *Device Description*

CalForma™ Calcium Sulfate Bone Graft Barrier is a pre-measured formulation containing a proprietary formulation of accelerated SGCSH and HPMC (surgical grade calcium sulfate [alpha] hemihydrate / hydroxypropyl methylcellulose [or hypromellose]) and a hydrating solution (sterile water).

### 4. *Indications For Use*

When mixed to the proper consistency using the pre-measured mixing solution supplied in each package, CalForma Calcium Sulfate Bone Graft Barrier can be formed over bony defects. When used over a bone graft, CalForma provides a stable barrier to graft material migration.

## 5. *Technological Characteristic Comparisons*

CalForma™ Calcium Sulfate Bone Graft Barrier is a modification of Lifecore Biomedical's CAPSET® Calcium Sulfate Bone Graft Barrier (K943186). The modification is the addition of a small amount of an excipient, HPMC, to the accelerated calcium sulfate in order to improve handling characteristics of the device when used as a barrier over bony defects in dental applications.

*In vitro* and *in vivo* testing demonstrated that this modification does not affect the safety or effectiveness of the device.

## 6. *Performance Data*

Animal testing established that the handling characteristics of CalForma™ were improved over the predicate, and that performance characteristics and safety were not affected by the modification.

## 7. *Biocompatibility*

*In vitro* and *in vivo* testing confirmed that the modified device is biocompatible.

## 8. *Conclusion (statement of equivalence)*

The data submitted in this 510(k) supports substantial equivalence of the modified device, CalForma™ Calcium Sulfate Bone Graft Barrier, to Lifecore Biomedical's CAPSET® Calcium Sulfate Bone Graft Barrier (K943186).

Substantial equivalence is based on the indications for use, primary ingredient, sterilization methods, instructions for use, and performance *in vivo*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2005

Mr. Jeremy Huotari
Project Manager
LifeCore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318-3051

Re: K042730
Trade/Device Name: CalForma™ Calcium Sulfate Bone Graft Barrier
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LYC
Dated: December 2, 2004
Received: December 16, 2004

Dear Mr. Huotari:

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.

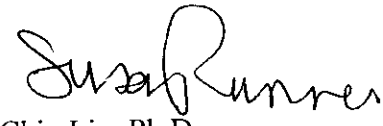
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

**Attachment C: Indications for Use Statement**

## INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K042730

**Device Name:** CalForma™ Calcium Sulfate Bone Graft Barrier

**Indications For Use:**

When mixed to the proper consistency using the pre-measured mixing solution supplied in each package, CalForma Calcium Sulfate Bone Graft Barrier can be formed over bony defects. When used over a bone graft, CalForma provides a stable barrier to graft material migration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Susan Runner

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

510(k) Number K042730