Lifecore Biomedical, Inc.
Special 510(k) Premarket Notification
Stage-1® Healing/Temporary Cap

JAN 23 2006

K053643

510(K) SUMMARY
[As required by 21 CFR 807.92(c)]

1. Submitter's Name and Contact Person

Lifecore Biomedical, Inc. 3515 Lyman Blvd Chaska, MN 55318	Brian Smekal Regulatory Affairs Specialist Ph: 952-368-6306; Fax: 952-368-4278

2. General Information

Trade Name	Stage-1® Temporary/Healing Cap
Common Name	Healing Abutment Cap, Temporary Cap
Classification Name	Endosseous Implant Abutment
Identification of Predicate Devices	• Stage-1® Cement-On Crown (COC) Abutment Healing Cap (K991114, K994205 and K003226) • PrimaConnex™ Quick-Abutment Temporary/Healing Cap (K051614)

3. Device Description

The Stage-1® Temporary/Healing Cap is a cap which is placed over the COC Abutment for protection during soft tissue healing. The Stage-1® Temporary/Healing Cap also offers a base for placement of a temporary crown. The temporary crown can be bonded directly to the Stage-1® Temporary/Healing Cap.

4. Intended Use

The Stage-1® Temporary/Healing Cap is placed after surgery to protect the Cement on Crown (COC) Abutment until the soft tissue has healed. It can be used alone or as the base for a temporary crown. The healing cap is intended for temporary use only up to 30 days.

5. Substantial Equivalence Comparison

Summary of how the **new Stage-1® Temporary/Healing Cap** is substantially equivalent to the **Stage-1® COC Abutment Healing Cap**:

- Have the same intended use,
- Incorporate the same basic healing cap design,
- Have the same shelf life, and
- Are packaged and sterilized using the same materials and processes.

Summary of how the **new Stage-1® Temporary/Healing Cap** is substantially equivalent to the **PrimaConnex™ Quick-Abutment Temporary/Healing Cap**:

- Have the same intended use,
- Incorporate the same basic healing cap design,
- Incorporate the same biocompatible materials,
- Have the same shelf life,
- And are packaged and sterilized using the same materials and processes.

In summary, the Stage-1® Temporary/Healing Cap described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2006

Lifecore Biomedical, Incorporated
Mr. Brian Smekal
Regulatory Affairs Specialist
Oral Restorative Division
3515 Lyman Boulevard
Chaska, Minnesota 55318-3051

Re: K053643
Trade/Device Name: Stage-1® Temporary/Healing Cap
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: NHA
Dated: December 29, 2005
Received: December 30, 2005

Dear Mr. Smekal:

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

Lifecore Biomedical, Inc.
Special 510(k) Premarket Notification
Stage-1® Temporary/Healing Cap

K053643

Indications for Use Statement

510(k) Number (if known):

Device Name: Stage-1® Temporary/Healing Cap

Indications for Use:

The Stage-1® Temporary/Healing Cap is placed after surgery to protect the Cement on Crown (COC) Abutment until the soft tissue has healed. It can be used alone or as the base for a temporary crown. The healing cap is intended for temporary use only up to 30 days.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (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)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

K053645