K072768

1 of 2

Section 8: 510(k) Summary (per 21 CFR 807.92(c))

OCT 23 2007

1. Submitter's Name and Contact Person

Lifecore Biomedical, Inc. 3515 Lyman Blvd Chaska, MN 55318	Karen Clement Regulatory Affairs Manager Ph: 952-368-6294; Fax: 952-368-4278

2. General Information

Trade Name	Restore®, Stage-1®, Renova®, PrimaSolo®, and PrimaConnex® Dental Implants
Common Name	Dental Implant
Classification Name	Endosseous Dental Implant
Identification of Predicate Devices	PrimaConnex Internal Connection Implants (K051614) PrimaSolo One-Piece Implants (K050506) Renova Internal Hex Implants (K032774) Stage-1 Single Stage RBM Implant (K003226) Restore (K002037, K95111, K944068)

3. Device Description

Lifecore Dental Implants are root-form, endosseous implants with a roughened surface. The modification proposed in this submission will modify the Resorbable Blast Media (RBM) implant surface to add a micro-texture surface morphology to the existing macrotexture. The change to the RBM surface will be incorporated into all Lifecore implant systems that have the RBM surface (Restore, Stage-1, Renova, PrimaSolo and PrimaConnex).

4. Intended Use

Lifecore's implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

5. Substantial Equivalence Comparison

A summary of how the **subject devices** are substantially equivalent to the **predicate devices** is provided below:

- All have the same intended use,
- All incorporate the same biocompatible materials,
- All incorporate the identical design,
- All have the same shelf life, and
- All are packaged and sterilized using the same materials and processes.

In summary, it is the belief of Lifecore Biomedical, Inc. that the subject implants described in this submission are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Ms. Karen Clement
Regulatory Affairs Manager
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318

Re: K072768
Trade/Device Name: Restore®, Stage-1®, Renova®, PrimaSolo®, and PrimaConnex® Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 27, 2007
Received: September 28, 2007

Dear Ms. Clement:

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.

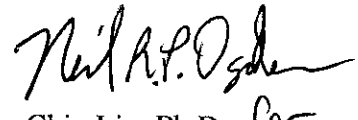
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072768

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The PrimaSolo One-Piece (3.0mm) Implant is a threaded one-piece implant with an integrated abutment designed for single-stage surgical procedure and is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. Mandible central and lateral incisors must be splinted if using two or more 3.0mm implants adjacent to one another.

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)

Susan Runner

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

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