APR 15 2005

K050506

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

1. Submitter's Name and Contact Person

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

2. General Information

Trade Name	Lifecore PrimaSolo™ One-Piece Implant System
Common Name	Endosseous dental implant system
Classification Name	Endosseous implant
Identification of Predicate Devices	• Restore® Self-Tapping Dental Implant System, RD (Lifecore Biomedical, Inc.) (K924589) • Restore® Self-Tapping Dental Implant System, WD (Lifecore Biomedical, Inc.) (K944068) • Restore® Self-Tapping Dental Implant System, SD (Lifecore Biomedical, Inc.) (K951111) • Altiva Immediate Function Dental Implant (Altiva Corporation) (K992512) • Replace® One Piece Implant (Nobel Biocare USA, Inc.) (K023952) • Nobel Direct (Nobel Biocare USA, Inc.) (K031345) • Biohorizons the Maestro System™ 3.0mm Diameter Implant (Biohorizons Implant System, Inc.) (K032351)

	• Renova™ Internal Hex Implant System (Lifecore Biomedical, Inc.) (K032774)

3. Device Description

The Lifecore PrimaSolo™ One-Piece Implant System is a one-piece implant incorporating both the implant and the abutment into one piece of machined titanium alloy. It is designed for one-stage surgical procedures and utilizes cement-retained restorations. It is designed to be used for immediate placement and temporization on single and multiple-tooth restorations. The system also includes healing caps and surgical instrumentation: tissue punches, twist drills, surgical taps, parallel pins, try-ins, surgical depth probe, latch-type implant drivers, and ratchet adapters . Lifecore PrimaSolo One-Piece Implants are available with a Resorbable Blast Media (RBM) roughened surface.

4. Intended Use

Lifecore Biomedical Dental Implant System 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

The Lifecore Biomedical PrimaSolo One-Piece Implant System and the predicate devices Restore® Self-Tapping Implant System (K924589, K944068 and K951111), Renova™ Internal Hex Implant System (K032774), Replace® One Piece Implant (K023952), Nobel Direct (K031345), Biohorizons the Maestro System™ 3.0mm Diameter Implant (K032351), and the Altiva Immediate

Function Dental Implant (K992512) the share a substantially equivalent intended use. The PrimaSolo and the predicate devices are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with roughened surfaces. The subject and predicate devices are similar in size and materials. All systems offer an integral abutment feature for cement retained restorations as well as associated accessories and instruments. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the PrimaSolo One-Piece Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Lifecore Biomedical, Incorporated
Ms. Rachel Kennedy
Regulatory Affairs Manager
Oral Restorative Division
3515 Lyman Boulevard
Chaska, Minnesota 55318-3051

Re: K050506
Trade/Device Name: PrimaSolo™ One-Piece Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: February 25, 2005
Received: March 2, 2005

Dear Ms. Kennedy:

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.

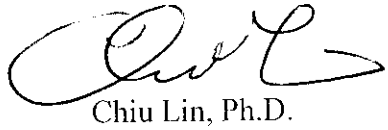
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K050506

Device Name: PrimaSolo™ One-Piece Implant System

Indications for Use:
Lifecore Biomedical Dental Implant System 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.

Specific Intended Uses: The PrimaSolo One-Piece (3.5 – 5.0mm) Implant is a threaded one-piece implant with an integrated abutment designed for single-stage surgical procedure and cemented restorations. The PrimaSolo One-Piece Implant is intended for immediate placement and can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone.

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)

Ken Mulley for MSR

(Division Sign-Off)

Division of General Hospital, Infection Control, Dental Devices

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