K051614

SEP - 9 2005

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 PrimaConnex™ Internal Connection 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) • Renova™ Internal Hex Implant System (Lifecore Biomedical, Inc.) (K032774) • PrimaSolo™ One-Piece Implant System (Lifecore Biomedical, Inc.) (K050506)

3. Device Description

The Lifecore Biomedical PrimaConnex Internal Connection Implant System consists of two-stage, root-form tapered and straight-walled threaded dental implants and associated abutment systems, which provide the clinician with

screw-retained, cement-retained, and overdenture abutments. The system also includes surgical and restorative instrumentation: twist drills, surgical taps, surgical depth probe, depth gauges, abutment drivers, latch-type drivers, and hand-piece adapters. Lifecore PrimaConnex implants are available with a Resorbable Blast Media (RBM) roughened surface. All implants have an internal connection as an anti-rotational feature for the prosthetics.

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.

The PrimaConnex™ Internal Connection Implant is a threaded implant that is intended for immediate placement and can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone.

5. Substantial Equivalence Comparison

The PrimaConnex Internal Connection Implant System has a substantially equivalent intended use as the identified predicates. All implants are intended for replacing missing teeth and supporting single or multiple-unit restorations in the mandible or maxilla. The Lifecore PrimaConnex Internal Connection Implants are similar in fundamental scientific technology to the predicate devices in that they are all threaded, root form implants constructed of titanium. The subject and predicate devices are similar in size and materials, are sterilized via gamma irradiation and intended for single use only. The PrimaConnex Internal Connection Implant System and the predicates include instruments to assist with the implant procedure. When compared with the predicate devices, no new

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questions of safety or effectiveness have been raised for the PrimaConnex Internal Connection Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Rachel Kennedy
Regulatory Affairs Manager
Lifecore Biomedical, Incorporated
3515 Lyman Blvd.
Chaska, Minnesota 55318-3015

Re: K051614
Trade/Device Name: PrimaConnex™ Internal Connection Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: June 16, 2005
Received: June 17, 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): K051614

Device Name: PrimaConnex™ Internal Connection 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.

The PrimaConnex Internal Connection Implant is a threaded internal connection implant. The PrimaConnex Internal Connection Implant is intended for immediate placement, where immediate implant placement is defined by the International Congress of Oral Implantologists (ICOI) as the placement of an implant at the time of tooth extraction, into the extraction socket.

The PrimaConnex Internal Connection Implant is intended for immediate provisionalization, non-occlusal load. Immediate Provisionalization is defined by the International Congress of Oral Implantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis with or without occlusal contact with the opposing dentition, at the same clinical visit of implant placement. The PrimaConnex Internal Connection Implant can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone.

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)

Susan Runner

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

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