K072241

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

NOV 09 2007

1. Submitter's Name and Contact Person

Lifecore Biomedical, Inc. 3515 Lyman Blvd Chaska, MN 55318	Judith Medlock-Hayes Regulatory Affairs Specialist Ph: 952.368.6364; Fax: 952.368.4278

2. General Information

Trade Name	Lifecore PrimaConnex® CAD/CAM Abutment System
Common Name	Endosseous dental implant abutment Ceramic Coping
Classification Name	**Abutment:** Endosseous dental implant abutment 21 CFR §872.3630, **Coping:** Porcelain Tooth 21 CFR §872.3290
Product Code	NHA, ELL
Identification of Predicate Devices	• DDS-ZR Zirconia (DDS Services) (K041645) • PrimaConnex Implant System (Lifecore Biomedical, Inc.) (K051614) • Atlantis Components' Abutment for Zimmer Internal Connection (Atlantis Components, Inc.) (K053373) • PrimaConnex Ceramic Copings (Lifecore Biomedical, Inc.) (K060530) • Atlantis Components' Abutment for Astra Implant (Atlantis Components, Inc.) (K070833)

3. Device Description

The PrimaConnex CAD/CAM Abutments and abutment-specific ceramic copings are placed onto the dental implant to provide support for a prosthetic restoration. The subject abutments are indicated for cemented restorations.

The abutments and copings are milled using computer-assisted technology that enables the creation of final abutments that are manufactured with specific geometry to meet individual anatomic variations in patient tooth and jaw structure.

4. Intended Use

The Lifecore PrimaConnex CAD/CAM Abutment System is intended for use as an accessory to a Lifecore PrimaConnex endosseous implant to support a prosthetic device in a partially or completely edentulous patient. They are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The copings are intended for use as a core structure for a prosthetic restoration in partially or fully edentulous mandibles and maxillae in the construction of single-unit cement retained restorations on Lifecore PrimaConnex CAD/CAM Abutments.

5. Substantial Equivalence Comparison

The PrimaConnex CAD/CAM Abutment System and predicate devices are substantially equivalent in intended use, material composition, fundamental scientific technology, principles of operation, and basic design. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the PrimaConnex CAD/CAM Abutment System.

Summary of Attachments

Attachment A: Device and Accessory Drawings

Attachment B: Static and Dynamic Fatigue Testing of Endosseous Dental Implant Systems – PrimaConnex® CAD/CAM Abutment System

Attachment C: Predicate Device Information

Attachment D: Declaration of Conformity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

Ms. Judith Medlock-Hayes
Regulatory Affairs Specialist
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318

Re: K072241
Trade/Device Name: PrimaConnex® CAD/CAM Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, ELL
Dated: August 10, 2007
Received: August 13, 2007

Dear Ms. Medlock-Hayes:

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

Indications for Use

510(k) Number (if known):

Device Name: PrimaConnex® CAD/CAM Abutment System

Indications for Use:

The Lifecore PrimaConnex® CAD/CAM Abutment System is intended for use as an accessory to a Lifecore PrimaConnex endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The copings are intended for use as a core structure for a prosthetic restoration in partially or fully edentulous mandibles and maxillae in the construction of single-unit cement retained restorations on Lifecore PrimaConnex CAD/CAM Abutments.

Prescription Use _X___ AND/OR Over-the-Counter Use _____

(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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