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

K073032

### *1. Submitter's Name and Contact Person*

| | |
|---|---|
| **Lifecore Biomedical, Inc.**<br>3515 Lyman Blvd<br>Chaska, MN 55318 | Judith Medlock-Hayes<br>Regulatory Affairs Specialist<br>Ph: 952-368-6364; Fax: 952-368-4278 |

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### *2. General Information*

| | |
|---|---|
| **Trade Name** | PrimaConnex® SD Esthetic Contour Zi Abutment |
| **Common Name** | Ceramic Abutment |
| **Classification Name** | Endosseous Implant Abutment |
| **Identification of Predicate Devices** | PrimaConnex RD and WD Esthetic Contour Zi Abutment, Lifecore Biomedical (K072572)<br><br>Esthetic Contour Straight and Angled Abutment for the PrimaConnex Internal Connection Implant System, Lifecore Biomedical (K051614)<br><br>PrimaConnex Ceramic Abutment, Lifecore Biomedical (K062876) |

### *3. Device Description*

PrimaConnex SD Esthetic Contour Zi Abutment is intended for use in conjunction with the PrimaConnex Internal Connection Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations.

### *4. Intended Use*

PrimaConnex SD Esthetic Contour Zi Abutment is intended for use in conjunction with the PrimaConnex Internal Connection Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations.

## 5. *Substantial Equivalence Comparison*

The summary of how the **PrimaConnex® SD Esthetic Contour Zi Abutment** is substantially equivalent to the **PrimaConnex RD and WD Esthetic Contour Zi Abutment** (K072572) is provided below:

- Both have the same intended use
- Both are manufactured from the same material
- Both incorporate the same design
- Both are packaged using the same materials and processes.

The summary of how the **PrimaConnex® SD Esthetic Contour Zi Abutment** is substantially equivalent to the **PrimaConnex Esthetic Contour Abutment** (K051614) is provided below:

- Both have the same intended use
- Both incorporate the same design
- Both are packaged using the same materials and processes.

The summary of how the **PrimaConnex® SD Esthetic Contour Zi Abutment** is substantially equivalent to the **PrimaConnex Ceramic Abutment** (K062876) is provided below:

- Both have the same intended use
- Both are manufactured from the same material
- Both incorporate the same design
- Both are packaged and using the same materials and processes.

In summary, it is the belief of Lifecore Biomedical, Inc. that the PrimaConnex SD Esthetic Contour Zi Abutment described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

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

Re: K073032
Trade/Device Name: PrimaConnex SD Esthetic Contour ZiAbutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: October 25, 2007
Received: October 29, 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.

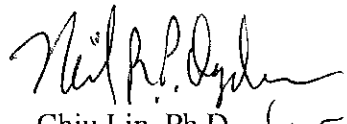
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

# Attachment B: Indications for Use Statement

**510(k) Number (if known):**

**Device Name:** PrimaConnex SD Esthetic Contour Zi Abutment

**Indications for Use:**

PrimaConnex SD Esthetic Contour Zi Abutment is intended for use in conjunction with the PrimaConnex Internal Connection Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations.

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)

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

510(k) Number: K073032

Page 1 of 1