K970776

MAY 27 1997

LIFECORE
BIOMEDICAL

510(k) Summary

VII Summary of Safety and Effectiveness
As required by 807.92(c).

1. This summary of Safety and Effectiveness is being submitted by:
Lifecore Biomedical, Inc.
3515 Lyman Blvd
Chaska, MN 55318
(612) 368 4300
Fax: (612) 368 3411

Contact Person: Donna Bahls
Regulatory Affairs Manager,
Oral Restorative Division

Date: December 13, 1996

2. Trade Name: Lifecore O-Ring Abutment and Lifecore Dalla Bona Abutment
Common Name: Overdenture Abutment
Classification Name: Attachment accessory for Class III Endosseous Implants (per 21 CFR 872.3165).

3. Equivalent Device: The device is substantially equivalent to the commercially marketed products known as Lifecore Overdenture Abutments Systems (K921764, K924190).

4. Device Description: The abutment is designed for use with an endosseous implant which is implanted in the lower or upper jaw. The abutment is used as an attachment solution to overdentures.

5. Intended Use: Implant systems are for use in edentulous mandibles and maxillae as a support or attachment for prosthetic restoration..

6. The technological characteristics of the modified versions of the o-ring and dalla bona abutments and the earlier versions are identical. The titanium used in both devices is the same. Manufacturing processes are also the same as is general shape and structure. Therefore, no new types of technology and no new technological questions are involved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1997

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

Re: K970776
Trade Name: Lifecore O-Ring Abutment; Lifecore Dalla Bona Abutment
Regulatory Class: III
Product Code: DZE
Dated: February 27, 1997
Received: March 4, 1997

Dear Ms. Bahls:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

The Lifecore Sustain and Restore Dental Implant Systems are intended for use in either partially or fully edentulous mandibles or maxillae in the following areas:

- Support of fixed (cemented) restorations utilizing multiple abutments;
- Support of fixed detachable (screw retained) prosthetics utilizing multiple abutments;
- Overdenture retention by means of a ball overdenture attachment, o-ring attachment, dalla bona or hader bar;
- Terminal or intermediate abutment support for fixed bridgework;
- Free standing restorations without involvement of adjacent dentition.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971076