

MAR - 8 2000

K993894

## Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

### 1. Submitter's Name / Contact Person

Carolyn Anderson  
Regulatory Specialist  
Lifecore Biomedical, Inc.  
3515 Lyman Blvd.  
Chaska, MN 55318  
Ph: 612-368-6324  
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### 2. General Information

<b>Trade Name</b>	<ul style="list-style-type: none"><li>• Lifecore Small Diameter (SD) Single Tooth Abutment with cuff heights of 1mm, 2mm, 3mm, and 4mm</li><li>• Lifecore Regular Diameter (RD) Single Tooth Abutment with cuff heights of 1mm, 2mm, 3mm, and 4mm</li><li>• Lifecore Wide Diameter (WD) Single Tooth Abutment with cuff heights of 1mm, 2mm, 3mm, and 4mm</li><li>• Lifecore SD / RD Healing Cap for the Single Tooth Abutment with flare diameters of 5.0mm, 6.0mm, and 7.5mm</li><li>• Single Tooth Abutment Screw, Square, Gold (in SD, RD, and WD sizes)</li><li>• Single Tooth Abutment Screw, .048" Hex, Titanium (in SD, RD, and WD sizes)</li><li>• Lifecore WD Healing Cap for the Single Tooth Abutment with flare diameters 6.0mm and 7.5mm</li></ul>
<b>Common / Usual Name</b>	Single Tooth Abutment
<b>Classification Name</b>	Precision Attachment for use as an accessory for Class III Endosseous Implants (per 21 CFR 872.3165)
<b>Identification of Equivalent Devices</b>	Single Tooth Abutment System (STA™) (K965077), manufactured by Implant Innovations, and CeraOne® Abutment System (K910611), manufactured by Nobel Biocare

### 3. Device Description

The Lifecore Single Tooth Abutment System is designed for use with an endosseous dental implant and provides support and retention for cement-retained, single tooth restorations in the mandible or maxilla. The system consists of the single tooth abutments, abutment screws, healing caps, impression posts, and associated laboratory components. Most components are packaged separately to allow the

clinician to choose only those components required for each clinical situation. The Lifecore Single Tooth Abutment System has been designed to be dimensionally compatible with the Nobel Biocare CeraOne® Abutment System gold and ceramic sleeves. The single tooth abutments and healing caps are manufactured from titanium alloy (Ti 6Al-4V E.L.I.).

**4. Intended Use**

The Lifecore Single Tooth Abutment is intended to attach to an endosseous implant and provide support and retention for a single-tooth restoration in the mandible or maxilla.

**5. Technological Characteristic Comparisons**

The Lifecore Single Tooth Abutment System is substantially equivalent to the Single Tooth Abutment System (K965077), manufactured by Implant Innovations and the CeraOne® Abutment System (K910611), manufactured by Nobel Biocare. Compared to the predicate devices, the Lifecore Single Tooth Abutment System has the same intended use, all systems are intended to be used for single tooth restorations. In addition, both the Lifecore and predicate abutment systems utilize similar designs, materials, and accessories.

**6. Nonclinical Tests**

The Lifecore Single Tooth Abutment System has been tested to ensure that all design specifications have been met. Dimensional inspections are routinely performed, Electrochemical Corrosion Evaluation of Uncoupled and Coupled Implant and Restorative Alloys has been performed to determine corrosion properties when exposed to artificial saliva and to determine the galvanic corrosion properties of the Precious Alloy/CP titanium and Precious Alloy/Ti-6Al-4V galvanic couples. All have been found to be within acceptable limits.

To ensure the Lifecore Single Tooth Abutment System design is compatible with the Nobel Biocare CeraOne® Abutment System Ceramic and Gold Sleeves, the critical mating dimensions of the CeraOne abutment, ceramic, and gold sleeves were measured using a Mycrona Video Measuring Machine and micrometers. The dimensional range for each component was determined. The Lifecore Single Tooth Abutment and Single Tooth Gold Sleeve were designed to match or to be within the dimensional ranges identified.

**7. Substantial Equivalence Comparison**

The Lifecore Single Tooth Abutment System is substantially equivalent to the following products:

<b>3i single Tooth Abutment System (STA or ST Abutment)</b>	<b>Nobel Biocare CeraOne Abutment System</b>
Implant Innovations, Inc. 4555 Riverside Dr. Palm Beach Gardens, FL 33410	Nobel Biocare 333 West Wacker Dr. Suite 2600 Chicago, IL 60606
Premarket Notification Number: K965077	Premarket Notification Number: K910611

### **8. Conclusion (statement of equivalence)**

The data submitted in this 510(k) is in support of substantial equivalency of Lifecore Single Tooth Abutment System to the following commercially marketed devices:

- 3i Single Tooth Abutment System (STA™) (K965077)
- Nobel Biocare CeraOne® Abutment System (K910611)

These current products as defined by their product literature, demonstrate the basis for the substantial equivalency relative to indications, materials, and design. The intended use of these devices is the same as the Lifecore Single Tooth Abutment System. The compatibility analysis demonstrates the substantial equivalence of Lifecore Single Tooth Abutment System to the predicate devices that are in commercial distribution.

**MAR - 8 2000**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Carolyn Anderson  
Regulatory Specialist  
Lifecore Biomedical, Inc.  
3515 Lyman Boulevard  
Chaska, Minnesota 55318-3051

Re: K993894  
Trade Name: Lifecore Single Tooth Abutment System  
Regulatory Class: III  
Product Code: DZE  
Dated: February 23, 2000  
Received: February 25, 2000

Dear Ms. Anderson:

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.

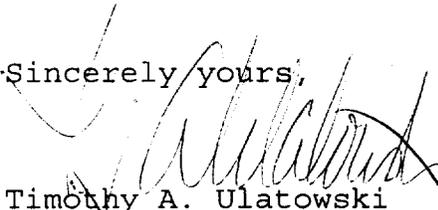
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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) 594-4690. 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 STATEMENT

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510(k) Number (if known): K993894

Device Name:  
Lifecore Single Tooth Abutment System

Indications for Use:

The Lifecore Single Tooth Abutment is intended to attach to an endosseous implant and provide support and retention for a single-tooth restoration in the mandible or maxilla.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Punno*

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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K993894