JUL 14 1999

K991114

Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. *Submitter's Name / Contact Person*

Carolyn Anderson
Ph: 612-368-6324
Fax: 612-368-4278.

2. *General Information*

Trade Name	• Single Stage Implant, TPS, 4.1mm, 1.8mm Collar (RDS) • Single Stage Implant, TPS, 4.1mm, 2.8mm Collar (RDS) • Single Stage Implant, TPS, 4.8mm, 1.8mm Collar (RDS) • Single Stage Implant, TPS, 4.8mm, 2.8mm Collar (RDS) • Indexed Abutment System (RDS) • COC Abutment System (RDS) • O-Ring Abutment System (RDS)
Common / Usual Name	Single Stage Dental Implant
Classification Name	Endosseous Implant
Identification of Equivalent Devices	ITI 4.1mm Solid Screw Implant and Accessories (K894595, K920768), manufactured by Straumann Dental, and Restore Self-Tapping Implant System (K 924589), manufactured by Lifecore Biomedical, Inc.

3. *Device Description*

The Regular Diameter Single Stage (RDS) TPS Dental Implant System consists of the single-stage, root-form dental implants and associated abutment systems, which provide the clinician with cement-retained, screw-retained and overdenture-type restorative options. The system also includes surgical and restorative instrumentation: drills, surgical taps, surgical depth probe, depth gauges, abutment drivers, latch-type drivers, open end wrench and handpiece adapters. The implants, prosthetics, *and* surgical tools are each packaged separately to allow the clinician to choose only those components required for each clinical situation. The single-stage implant is titanium plasma spray coated on the portion of the implant that is submerged into bone. The non-submerged portion is machined smooth to allow for the attachment of epithelial tissue. This surgical procedure eliminates the need for the second (uncovery) surgery that is required in two-stage implant systems.

4. *Intended Use*

Lifecore's Single Stage Dental Implant system is intended for use in either partially or fully edentulous mandibles and maxillae in the following areas:

- Support of fixed (cement retained) restorations utilizing abutment options.
- Support of fixed detachable (screw retained) prosthetics utilizing multiple abutment options.
- Overdenture retention by means of an o-ring or bar appliance.
- Terminal or intermediate abutment support for fixed bridgework.
- Free standing restorations without involvement of adjacent dentition when the locking taper is engaged.

5. Technological Characteristic Comparisons

	Subject Device	**Predicate Devices**	
Feature	Lifecore Regular Diameter Single Stage (RDS) TPS Dental Implant	ITI 4.1 mm Solid Screw Implant (K894595, K920768)	Restore Self-Tapping Implant (K924589)
Intended Use	Identical to predicate devices	Surgical placement in maxillary and/or mandibular arch to support crowns, bridges, overdentures in edentulous or partially edentulous patients	Indicated for single edentulous spaces, large edentulous segments between teeth, unilateral and bilateral free-end saddle areas, and the totally edentulous mandibles and maxillae.
Material:	CP Titanium (Grade 4)	CP Titanium (Grade 4)	CP Titanium (Grade 3)
Design			
External screw threads	YES	YES	YES
Implant Body Diameter (mm)	4.1, 4.8	4.1, 4.8	3.75, 4.0
Shoulder Diameter (mm)	4.8	4.8	4.089
Collar Height (mm)	1.8, 2.8	1.8, 2.8	0.81
Lengths	8.0, 10.0, 12.0, 14.0, 16.0	8.0, 10.0, 12.0, 14.0, 16.0	8.0, 10.0, 11.5, 13.0, 15.0, 18.0
One stage	YES	YES	NO
Implant/abutment interface	Locking Taper	Locking Taper	External Hex
Cutting Flute	YES	NO	YES
TPS Coating	YES	YES	NO
Gamma sterilized	YES	YES	YES
Attachments			
Screw-retained restoration system	YES (Indexed Abutment System)	YES (Octasystem®)	YES (ONE System Abutment, UCLA Abutment System)

Cemented restoration system	YES (RDS COC Abutment System)	YES (Solid Abutment System)	YES (COC Abutment System)
Overdenture restoration system	YES (RDS O-Ring Abutment System)	YES (Retentive Anchor System)	YES (Dalla Bona and O-Ring Abutment Systems)
Instruments (surgical and restorative)	YES	YES	YES

6. *Nonclinical Tests*

The RDS TPS Dental Implant System has been tested to ensure that all design specifications have been met. Dimensional inspections are routinely performed, Abrasion testing to ensure TPS coating strength, 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, and the Mechanical Properties of the Plasma Spray Coating have been analyzed. All have been found to be within acceptable limits.

7. *Substantial Equivalence Comparison*

The RDS TPS Dental Implant System is substantially equivalent to the following products:

ITI 4.1 mm Solid Screw Implant and Accessories	Restore Self-Tapping Implant System
Institut Straumann AG CH-4437 Waldenburg Switzerland	Lifecore Biomedical, Inc. 3515 Lyman Blvd. Chaska, MN 55318
Premarket Notification Number: K894595, K920768	Premarket Notification Number: K924589

8. *Conclusion (statement of equivalence)*

The data submitted in this 510(k) is in support of substantial equivalency of the Lifecore Regular Diameter Single Stage (RDS) TPS Dental Implant System to the following commercially marketed devices:

- ITI 4.1 mm Solid Screw Implant (K894595, K920768)
- Restore Self-Tapping Implant (K924589)

These current products as defined by their product literature, demonstrate the basis for the substantial equivalency relative to indications, materials, design, and surface characteristics. The intended use of these devices is the same as the Lifecore RDS TPS Dental Implant System. The comparative analysis demonstrates the substantial equivalence of the Lifecore RDS TPS Dental Implant System to the predicate devices that are in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Ms. Carolyn Anderson
Regulatory Specialist
Lifecore Biomedical, Incorporated
3515 Lyman Boulevard
Chaska, Minnesota 55318

Re: K991114
Trade Name: Regular Diameter Single Stage (RDS) TPS Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: March 31, 1999
Received: April 1, 1999

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 (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 STATEMENT

510(k) Number (if known): _____

Device Name:
Regular Diameter Single Stage (RDS) TPS Dental Implant System

Indications for Use:

- The Regular Diameter Single Stage TPS Dental Implant System is indicated for use in support of crowns, bridges, or overdentures in completely and partially edentulous maxilliary and mandibular arches in areas with sufficient alveolar bone width and height to surround the submerged portion of the implant with at least 1mm of bone, both buccally and lingually.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K00 1114