K982305

SEP 22 1998

510(K) SUMMARY

Pursuant to 513(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Sulzer Calcitek Inc.
Address:	2320 Faraday Avenue, Carlsbad, CA 92008
Telephone Number:	(760) 431-9515
Registration Number:	2023141
Contact Person:	Foster Boop
Date Summary Prepared:	June 30, 1998
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Temporary Prosthetic Component
Device Trade Name:	Spline Dental Implant System - Temporary Abutment

The primary device used for comparison purposes in this summary is the Spline Dental Implant System – Fixed Abutment

1. **Intended Use:**
The statements of intended use are identical with the exception that the duration of Temporary Abutment use is limited. Temporary Abutments are intended to be used in the same manner as their permanent counterpart except that the former are used to support temporary (provisional) restorations.

2. **Description:**
The Spline Dental Implant System - Temporary Abutment will consist of a titanium alloy abutment cylinder with a separate titanium alloy retaining screw. A Temporary Abutment will attach directly to the Spline implant with the retaining screw but does not engage the tines. It will be available in three different cuff diameters at the abutment/implant interface: 3.25mm, 4.0mm and 5.0mm. Abutments will also be available with straight wall or stepped cuffs with either a straight or a tapered retentive wall.

3. **Technological Characteristics:**

The Temporary Abutments have the same technological characteristics as the predicate device.

4. **Performance Data:**
Bench top testing demonstrate the substantial equivalence of the Temporary Abutment to the predicate device.

5. **Comparison Analysis:**

The overall design of the Temporary Abutment is identical to the predicate device.

SUMMARY OF COMPARISON		
Feature	**Temporary Abutment**	**Predicate Device**
Available Diameters	3.25mm, 4.0mm & 5.0mm	3.25mm, 4.0mm & 5.0mm
Material	Titanium alloy	Titanium alloy
Manufacturing site	Sulzer Calcitek, Carlsbad, CA.	Sulzer Calcitek, Carlsbad, CA.
Packaging	tray with tyvek lid	tray with tyvek lid
Sterility	Non-sterile	Non-sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Mr. Foster Boop
Regulatory Affairs Associate
Sulzer Calcitek, Incorporated
2320 Faraday Avenue
Carlsbad, California 92008

Re: K982305
Trade Name: Spline™ Dental Implant System - Temporary Abutments
Regulatory Class: III
Product Code: DZE
Dated: June 30, 1998
Received: July 1, 1998

Dear Mr. Boop:

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,

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

Enclosure

510(K) Number (if known): _____

Device Name: Temporary Abutment

Indications For Use:

A Temporary Abutment is indicated for use for a maximum of six weeks as an abutment for cemented provisional prostheses. This abutment can be used for single tooth provisional restorations or splinted to other abutments for multi-unit provisional restorations. Single 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 Dental, Infection Control, and General Hospital Devices
510(k) Number K982305

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)