JUN 16 1999

K984536

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:	December 18, 1998
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant Abutment
Device Trade Name:	Removable Cuff Abutment

The primary devices used for comparison purposes in this summary are Spline™ and Omniloc® Abutments: Fixed, 15 and 25 degree pre-angled.

1. **Intended Use:**
   Intended use of a Removable Cuff Abutment is similar to the intended use of the predicate abutments. They are screw retained abutments for endosseous dental implants and function as anchors to which prosthetic devices, such as single crowns or bridges, are attached to restore a patient's chewing function. A Removable Cuff Abutment can serve as an anchor for cement retained or screw retained prosthetic devices. Predicate abutments can only serve as anchors for cement retained prostheses.

2. **Description:**
   A Removable Cuff Abutment is a two piece titanium alloy abutment with a separate titanium alloy retaining screw. Each Removable Cuff Abutment is composed of one abutment core body and one removable cuff. Removable Cuff Abutments will be offered as fixed abutments and as pre-angled (15 and 25 degree) abutments for use with both cement and screw retained prosthetics. Abutments will be available in three different diameters at the abutment/implant interface: 3.25mm, 4.0mm and 5.0mm. Flare diameters of cuffs will range from 4.0 to 6.5mm and cuff heights will range from 0.5 mm to 5mm. A new feature is the addition of a transverse (lingual) screw to some designs. This feature will permit attachment of screw retained prostheses in addition to cement retained prostheses. Removable Cuff Abutments will be packaged with or without the transverse (lingual) screw components.

3. **Technological Characteristics:**
   Removable Cuff Abutments have the same technological characteristics as the predicate devices.

4. **Performance Data:**
Bench top testing demonstrated the equivalence of the Removable Cuff Abutment to the predicate devices.

5. **Comparison Analysis:**

The overall design of the Removable Cuff Abutment is similar to the predicate devices.

SUMMARY OF COMPARISON		
Feature	**Removable Cuff Abutment**	**Predicate Abutments**
Abutment Options	Fixed, 15^0 and 25^0 pre-angled	Fixed, 15^0 and 25^0 pre-angled
Available Diameters	3.25mm, 4.0mm & 5.0mm	3.25mm, 4.0mm & 5.0mm
Cuff Flare Diameters	4.0 to 6.5mm	4.0 to 6.5mm
Cuff Heights	0.5 mm to 5.0mm	0.5 to 5.0mm
Transverse (lingual) screw	Yes	No
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

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990: and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (Class III Summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (Class III Certification), as described in Sec. 807.94.

A Class III Certification and Summary is provided on the following pages.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1999

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

Re: K984536
Trade Name: Removable Cuff Abutment
Regulatory Class: III
Product Code: DZE
Dated: March 19, 1999
Received: March 22, 1999

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,

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: Removable Cuff Abutments

Indications For Use:

Removable Cuff Abutments are screw retained endosseous dental implant abutments and are intended to function as an anchor to which prosthetic devices may be attached using either dental cement or a lingual screw.

They are indicated for use on endosseous implants placed in the mandible or maxilla for support of fixed bridgework, removable bridgework or free standing single tooth replacements.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984536