JUN 23 1997 K970752

510(K) SUMMARY
RELEASABLE THROUGH FREEDOM OF INFORMATION

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:	(619) 431-9515
Registration Number:	2023141
Contact Person:	Joseph S. Shan
Date Summary Prepared:	February 27, 1997

Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant Abutment
Device Trade Name:	Spline Engaging Shouldered Abutment System

The primary device used for comparison purposes in this summary is Sulzer Calcitek's existing Spline Dental Implant System. All implant systems are manufactured in the same facility located in Carlsbad, California.

1. **Intended Use:**
   For use when screw retention of a single or splinted prosthesis is desired, e.g., single crown, bars and bridges. Implants must be within 30° of parallelism to each other for a splinted prosthesis.

2. **Description:**
   The Spline Engaging Shouldered Abutment System provides an anti-rotational option for single or multiple tooth prosthetic restorations. The components of this system are supplied non-sterile, for use by licensed dentists.

3. **Technological Characteristics:**
   There has been a modification to the shouldered abutment and associated components. Both the implant/abutment and abutment/coping interface engage the spline tines, providing anti-rotation. There has been no change to the materials of this device.

4. **Comparison Analysis:**
   The overall design of the prosthetic components are similar or identical to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1997

Mr. Joseph S. Shan
Regulatory Affairs Associate
Sulzer Calcitek Incorporated
2320 Faraday Avenue
Carlsbad, California 92008

Re: K970752
Trade Name: Spline Engaging Shouldered Abutment System
Regulatory Class: II
Product Code: DZE
Dated: February 28, 1997
Received: March 3, 1997

Dear Mr. Shan:

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) 594-4618. 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 at (301) 443-6597.

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

Spline Engaging Shouldered Abutment System

INDICATIONS FOR USE

Spline Engaging Shouldered Abutment System

For use when screw retention of a single or splinted prosthesis is desired, e.g., single crown, bars and bridges. Implants must be within 30° of parallelism to each other for a splinted prosthesis.

Sulzer Calcitek Dental Implant Systems

Sulzer Calcitek Dental Implant Systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement. The use of the 5.0mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970752

Prescription Use ✓
(Per 21 CFR 801.109)

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