K973521

NOV 20 1997

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:	(760) 431-9515
Registration Number:	2023141
Contact Person:	Foster Boop
Date Summary Prepared:	September 10, 1997
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant System
Device Trade Name:	Variable Parallel Pin

1. **Predicate Devices**:
   Sulzer Calcitek's Parallel Pins.
   Nobelpharma BRANEMARK SYSTEM® Abutment Selection Kit

2. **Intended Use:**
   The Variable Parallel Pin is intended to provide a visual reference for evaluating parallelism, prosthetic fit and implant spacing between implants and natural teeth during implant placement surgery.

3. **Description:**
   The Variable Parallel Pin consists of two pivoting pegs that lock in orientations from straight (0^0) to 25^0. The Variable Parallel Pin has cuff width geometry's that match the flare diameters of prosthetic abutments.

4. **Technological Characteristics:**
   The technological characteristics between the Variable Parallel Pin and the predicate devices are identical. The addition of a hinging mechanism combines the function of fixed angle pins into a single pin.

5. **Comparison Analysis:**
   The overall design of the Variable Parallel Pin is similar or identical to the predicate devices. The Variable Parallel Pin is substantially equivalent to the predicate devices in design, manufacturing, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV 20 1997

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

Re: K973521
Trade Name: Variable Parallel Pin
Regulatory Class: III
Product Code: DZE
Dated: September 15, 1997
Received: September 17, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 (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): K973521

Device Name: Variable Parallel Pin

Indications For Use:

The Variable Parallel Pin is indicated for use in evaluating parallelism up to 25 degrees and to gauge implant spacing and fit of prosthetics with cuff flare diameters 6.5mm or less between implants and adjacent natural teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Gerald Shipley
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973521

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

(Optional Format 1-2-96)