K970127

JUN 23 1997

Calcitek HA-Coated Endosseous Dental Implants
January 1997

510(k) SUMMARY
INFORMATION - RELEASABLE THROUGH FOI

Summary of Information Concerning Safety and Effectiveness for Purposes of establishing Substantial to a Predicate Device Pursuant to 513(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Calcitek, Inc.
Address:	2320 Faraday Avenue, Carlsbad, CA 92008
Telephone Number:	(619) 431-9515
Registration Number:	2023141
Contact Person:	Donna K. Howard
Date Summary Prepared:	December 1996

Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant System
Device Trade Name:	Calcitek HA-Coated Endosseous Dental Implant Systems

The primary devices used for comparison purposes in this summary are Calcitek's existing HA-coated endosseous dental implant systems. All implant systems are manufactured in the same facility located in Carlsbad, California.

1. **Intended Use:** The statements of intended use are identical.

   "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."

2. **Description:** These Class III dental implants are supplied sterile, ready for placement by a licensed dentist.

3. **Technological Characteristics**

   Design: There has been no change to the design of these implants.

   Materials: The materials used for the dental implants are the same as previously mentioned in the premarket notifications.

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4. **Comparison Analysis:**

The overall design of the implants is identical to the predicate devices. The composition of the HA coating has been changed. The crystalline HA content has been enhanced and the content of all non-HA components has been decreased.

T-826 P.04 F-260 7604319753 APR 01 97 13:30 FROM:CALCITEK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1997

Ms. Donna K. Howard
Supervisor, Clinical Affairs
Sulzer Calcitek Incorporated
2320 Faraday Avenue
Carlsbad, California 92008-7216

Re: K970127
Trade Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: January 10, 1997
Received: January 14, 1997

Dear Ms. Howard:

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

510(k) Number (if known): K970127

Device Name: HA coated Endosseous Dental Implant

Indications For Use:

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970127

Prescription Use X/12 OR Over-The-Counter Use No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)