

JUL 30 1998

K981562

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: April 30, 1998
Classification Name: Implant, Endosseous (76DZE)
Common/Usual Name: Dental Implant System
Device Trade Name: Spline Dental Implant System – Spline XI

The primary device used for comparison purposes in this summary is Sulzer Calcitek's existing Spline Dental Implant System: HA-coated threaded implants and uncoated textured self-tapping threaded implants. All implant systems are manufactured in the same facility located in Carlsbad, California.

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

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.

2. **Description:**

Spline XI implants are available both with and without HA-coating. They are available in 3.75mm or 5.0mm diameters and are available in five lengths: 8, 10, 13, 15 and 18mm. A total of four surface styles are available: HA-coated, HA-coated/textured, HA-coated/machined and textured/machined. The implants are supplied sterile.

3. **Technological Characteristics:**

There has been a modification to the apical portion of the implant body to provide the implant with self-tapping capabilities. The implant/abutment interface remains unchanged. There has been no change to the materials of this device or to the implant/abutment interface.

4. **Comparison Analysis:**

The overall design of the Spline XI implants are identical to the predicate implants.

SUMMARY OF COMPARISON		
Feature	Spline XI implant	Predicate Implants
Implant body geometry	screw type endosseous implants	screw type endosseous implants
Implant lengths	8, 10, 13, 15, 18mm	8, 10, 13, 15, 18mm
Implant diameters	3.75, 5.0mm	3.75, 5.0mm
Implant body material	Titanium alloy	Titanium alloy
Implant/abutment interface	spline – 6 tines	spline – 6 tines
Manufacturing site	Carlsbad, CA	Carlsbad, CA
HA Coating	Available on some designs	Available on some designs
Sterile	Yes	Yes

Spline Dental Implant System – Spline XI

- (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.

Spline Dental Implant System – Spline XI

PREMARKET NOTIFICATION
CLASS III CERTIFICATION AND SUMMARY

(As Required by 21 CFR 807.94)

I certify, in my capacity as Regulatory Affairs Associate, of Sulzer Calcitek Inc, that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the endosseous dental implant. I further certify that I am aware of the types of problems to which the endosseous dental implant is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the endosseous dental implant is complete and accurate. Such search is defined as examining:

- the FDA proposal to require the filing of premarket approval applications (PMAs) for endosseous dental implants, section D, "Degree of Risk," (Federal Register, Vol. 54, No. 234, 12/7/89, p. 50593).
- article titles and abstracts for the citations found when using search strategy for items which include dental implant(s) or endosseous, and fail?, complicat?, risk? hazard?, safety, effectiveness, side effect? adverse? problem? or success rate? using Medline database, 1989-present, accessed using PubMed at <http://www.ncbi.nlm.nih.gov> in March 1998.
- relevant company documents, including product labeling, concerning the safety and effectiveness information of endosseous implants.

Attached to this certification is a summary of and citation to the adverse safety and effectiveness data found in that search.

Name of individual signing the certification: Foster Boop

Signature: Foster Boop
Title: Regulatory Affairs Associate

Company Name: Sulzer Calcitek Inc.
Address: 2320 Faraday Avenue, Carlsbad, California 92008
Phone Number: (760) 431-9515

Date: April 30, 1998

Spline Dental Implant System – Spline XI

SUMMARY OF POSSIBLE COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS		
Reported Adverse S&E Information	Possible Causes	Citation
Local soft tissue degeneration	1) gingivitis 2) infection	· Federal Register (FR), 54 (234), 12/7/89, p. 50593. · Int J Oral Maxillofac Implants, Winter 1992, 7 (4), p. 477-84.
Bone resorption	1) infection (see below) 2) poor oral hygiene 3) mal-distribution of occlusal forces: a) poorly designed prosthetics (nonpassive fit, which may cause micro-movement, tension on the implants, and/or prosthetic loosening, overload, etc.) b) traumatic occlusal forces 4) inadequate bone at the time of placement 5) bone necrosis due to inadequate cooling during drilling	· Federal Register (FR), 54 (234), 12/7/89, p. 50593. · Dent Clin North Am, Jan 1992, 36 (1), p. 27-37. · J Osaka Univ Dent Sch, Dec 1990, 30, p. 86-96. · Quintessence Int, Dec 1992, 23 (12), p. 811-6. · J Prosthet Dent, Aug 1993, 70 (2), p. 135-40. · Curr Opin Periodontol, 1994, p. 194-204. · Int J Oral Maxillofac Implants, V10 N3, 1995, pp. 373-8. · Int J oral Maxillofac Implants, V10 N3, 1995 May-Jun, pp. 303-11. · Biomaterials, Aug 1995, 16(2), 917-20
Perforation of the maxillary sinus/oroantral fistula/oronasal fistula	1) poor bone quality 2) inadequate bone quantity or misjudgment of available bone 3) improper drill length selection	· Federal Register (FR), 54 (234), 12/7/89, p. 50593. · Dtsch Zahnarztl Z (Germany), Jan 1990, 45 (1), p. 58-60 · AORN J, Mar 1990, 51 (3), p. 729, 731, 733-4 passim. · J Oral Maxillofac Surg, Nov 1993, 5 (11), p. 1198-203.
Perforation of the labial and lingual plates	1) poor bone quality 2) inadequate ridge width 3) improper placement/alignment of device	· Federal Register (FR), 54 (234), 12/7/89, p. 50593.

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SUMMARY OF POSSIBLE COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS		
Reported Adverse S&E Information	Possible Causes	Citation
Paresthesia/nerve injury	1) improper placement of device causing impingement of the nerve 2) poor bone quality allowing accidental displacement into the mandibular canal 3) repositioning of the nerve for placement of the device 4) damage to the nerve during drilling of site	<ul style="list-style-type: none"> · Federal Register (FR), 54 (234), 12/7/89, p. 50593. · Int J Oral Maxillofac Implants, Fall 1991, 6 (3), p. 264-9. · Oral Surg Oral Med Oral Pathol, Jul 1990, 70 (1), p. 24-8. · Ohio Dent J, Spring-Summer 1992, 66 (1), p. 16-7, 19-25. · J Prosthet Dent, Oct 1992, 68 (4), p. 664-71. · Int J Oral Maxillofac Implants, Spring 1992, 7 (1), p. 45-50. · Int J Oral Maxillofac Implants, Mar-Apr 1994, 9 (2), p. 249-54. · J Oral Maxillofac Surg, V53 N3, 1995 Mar, pp. 264-8. · J Prosthetic Dent Dec 1997, 78(6), p. 537-41
Exfoliation (post-restoration)	(See bone resorption risk above) 1) infection (see below) 2) poor oral hygiene 3) mal-distribution of occlusal forces: a) poorly designed prosthetics (nonpassive fit, which may cause micro-movement, tension on the implants, and/or prosthetic loosening, overload, etc.) b) traumatic occlusal forces 4) inadequate bone at the time of placement 5) bone necrosis due to inadequate cooling during drilling	<ul style="list-style-type: none"> · Federal Register (FR), 54 (234), 12/7/89, p. 50593. · J Prosthet Dent, Feb 1992, 67 (2), p. 236-45. · J Parodontol, May 1991, 10 (2), p. 219-25. · Pract Periodontics Aesthet Dent, Aug 1993, 5 (6), p. 11-20. · Int J Oral Maxillofac Implants, 1993, 8 (1), p. 92-7. · Int J Oral Maxillofac Implants, V10 N1, 1995 Jan-Feb, pp. 33-42. · Biomaterials V16 N12, Aug 1995, pp. 917-920. · J Oral Maxillofac Surg, V52 N9, PP. 937-43. · Int J Oral Maxillofac Implants, Jan-Feb 1995, V10 N1, pp. 74-8, 89-98.

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SUMMARY OF POSSIBLE COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS		
Reported Adverse S&E Information	Possible Causes	Citation
Local and systemic infection	1) poor oral hygiene 2) contaminated surgical field 3) device not sterile	<ul style="list-style-type: none"> · Federal Register (FR), 54 (234), 12/7/89. p. 50593. · Clin Oral Implants Res, Dec 1992, 3 (4), p. 162-8. · J Oral Implantol, 1993, 19 (4), p. 321-35. · J Periodontol V66 N1, 1995 Jan, pp. 69-74. · Int J Oral Maxillofac Implants V9 N2, 1994 mar-Apr, pp. 197-206. · Head Neck, Mar-Apr 1996, 18 (2), p. 192-6. · Int J Oral Maxillofac Implants, Mar-Apr 1996, 11(2), P. 205-9.
Maxillary sinusitis	perforation of the maxillary sinus	<ul style="list-style-type: none"> · J Oral Maxillofac Surg, Mar 1992, 50 (3), p. 285-7. · J Oral Implantol, 1992, 18 (1), p. 15-23. · J Laryngol Otol, Apr 1990 104(4), p. 333-4
Implant fracture	1) inadequate structural strength 2) inadequate bony support: <ul style="list-style-type: none"> a) insufficient bone at placement b) bone resorption 	<ul style="list-style-type: none"> · Federal Register (FR), 54 (234), 12/7/89. p. 50593. · Int J Oral Maxillofac Implants, Fall 1989, 4 (3), p. 255-6. · Int J Oral Maxillofac Implants, 1993, 8 (4), p. 409-14. · Int J Oral Maxillofac Implants V10 N3, 1995 May-Jun, pp. 326-34. · Clin Oral Implants Res V5 N1, 1994 Mar, pp. 9-18.
Dental bur fracture	1) inadequate structural strength 2) improper use, including <u>not</u> drilling in an up-and-down motion	<ul style="list-style-type: none"> · Sulzer Calcitek customer feedback

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SUMMARY OF POSSIBLE COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS		
Reported Adverse S&E Information	Possible Causes	Citation
Abutment fracture	1) inadequate structural strength 2) inadequate bony support: a) insufficient bone at placement b) bone resorption 3) poorly designed prosthesis 4) traumatic or destructive occlusal forces	· Federal Register (FR), 54 (234), 12/7/89. p. 50593. · J Prosthet Dent, Jul 1992, 68 (1), p. 93-5. · J Oral Rehabil, Jul 1993, 20 (4), p. 413-22.
Hemorrhage	lacerations or transections of the facial and/or lingual arteries in the floor of the mouth during drilling	· J Am Dent Assoc., Nov 1990, 121 (5), p. 599-60. · J Oral Maxillofac Surg, Feb 1990, 48 (2), p. 201-4. · J Am Dent Assoc., Jan 1991, 122 (1), p. 22-4, 26-8. · Int J Oral Maxillofac Implants, 1993, 8 (3), p. 329-34.
Mandibular fracture	1) inadequate bone width 2) poor bone quality	· J Oral Maxillofac Surg, Mar 1990, 48 (3), p. 311-7. · Int J Oral Maxillofac Implants, Fall 1991, 6 (3), p. 264-9. · Acta Stomatol Belg V90 N4, 1993 Dec. pp. 251-8.
Air embolism ⁵	introduction of compressed coolant air via a surgical bur	· Can J Anaesth, Jan 1990, 37 (1), p. 112-21. · Int J Oral Implantol, 1989, 6 (1), p. 50-63. · J Periodontol, Jan 1992, 63 (1), p. 63. · Chest, Feb 1992, 101 (2), p. 561-2. · J Oral Rehabil V21 N6, 1994 Nov, pp. 721-2.

⁵ Investigation supported the hypothesis that air was introduced via the dental burs due to use of compressed coolant air driven systems. The College of Dental Surgeons of British Columbia has recommended to its members involved in the placement of implants that they review their technique to ensure that compressed air is not introduced into the surgical site via a surgical bur. A similar recommendation is included in the instructions for use of this product.

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SUMMARY OF POSSIBLE COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS		
Reported Adverse S&E Information	Possible Causes	Citation
Subcutaneous emphysema	introduction of air via cleaning instrument	Rev Belge Med Dent, 1991, 46 (3), p. 64-71.
Injury to adjacent teeth and supporting structures	1) damage to tooth root or surgical trauma during drilling or placement 2) poor prosthetic design 3) traumatic occlusion	· AORN J, Mar 1990, 51 (3), p. 729, 731, 733-4 passim. · Int J Oral Maxillofac Implants, Fall 1991, 6 (3), p. 270-6. · Int J Prosthodont, Jan-Feb 1990, 3 (1), p. 89-92. · J Dent, Aug 1993, 21 (4), p. 203-8.
Gingivitis	poor oral hygiene	· Ned Tijdschr Tandheelkd. Aug 1990, 97 (8), p. 327-31. · Shigaku, Oct 1989, 77 (SPEC) p. 1235-45. · J Prosthet Dent V72 N2, 1994 Aug, pp. 144-51.
Hyperplasia formation/granuloma	1) exuberant healing process 2) poor oral hygiene	· Int J Oral Maxillofac Implants, Summer 1991, 6 (2), p. 215-7. · Shigaku, Oct 1989, 77 (SPEC) p. 1235-45. · Clin Oral Implants Res, Dec 1992, 3 (4), p. 149-61. · Implant Dent, Spring 1993, 2 (1), p. 27-30.
Delayed healing/ failure to integrate (exfoliation prior to restoration)	1) poor bone quality or other patient factors (e.g., systemic disease, excessive tobacco/alcohol use, etc.) 2) healing not passive 3) site not properly prepared 4) inadequate bone at the time of implant placement 5) bone necrosis due to inadequate cooling during drilling 6) infection	· Int J Oral Maxillofac Implants, Fall 1990, 5 (3), p. 272-81. · J Periodontol, Apr 1993, 64 (4), P. 306-10. · Int J Oral Maxillofac Implants, 1993, 8 (1), p. 92-7. · Calcitek product labeling · J Prosthet Dent V71 N4, 1994 Apr, pp. 375-8. · J Endo (United States), Mar 1996, 22 (3), p. 135-9.

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SUMMARY OF POSSIBLE COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS		
Reported Adverse S&E Information	Possible Causes	Citation
Hyperesthesia/Hypoesthesia	1) improper placement of device involving impingement of the nerve 2) repositioning of the nerve for device placement 3) damage to the nerve during drilling 4) poor bone quality allowing accidental displacement into the mandibular canal	· Sulzer Calcitek product labeling
Laryngeal obstruction, pneumothorax	screwdriver (tool) aspiration	· Int J Oral Maxillofac Surg, Dec 1992, 21 (6), p. 339-41 · Int J Oral Maxillofac Surg, Sept 1996, 11 (5), p. 679-81.
Edema, hematoma	possible surgical side effects	· Sulzer Calcitek product labeling
Mal-positioned implants	1) poor bone quality allowing accidental displacement 2) insufficient bone quantity	· Sulzer Calcitek customer feedback · J Prosthet Dent V71 N4, 1994 Apr, pp. 359-63. · J Oral Maxillofac Surg V52 N9, 1994 Sep, pp. 937-43. · Int J Oral Maxillofac Implants, Jul-Aug 1995, V10 N4, pp. 485-90.
Psychological rejection of implants	poor patient screening	· Sulzer Calcitek customer feedback
Local and generalized allergic reaction ⁶	hypersensitivity	· Sulzer Calcitek product labeling

⁶ No reports of allergic reaction have been received to date.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1998

Mr. Foster Boop
Regulatory Affairs Associate
Sulzer Calcitek, Incorporated
2320 Faraday Avenue
Carlsbad, California 92008-7216

Re: K981562
Trade Name: Spline Dental Implant System - Spline XI
Regulatory Class: III
Product Code: EBF
Dated: April 30, 1998
Received: May 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 (Pre-market 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 pre-market 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.

Page 2 - Mr. Boop

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,

S. Antman 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

