SEP - 6 2001

K012055

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Sulzer Dental Inc.
Address:	1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number:	760-431-9515
Registration Number:	2023141
Contact Person:	Foster Boop
Date Summary Prepared:	September 5, 2001
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant
Device Trade Name:	3.15mm Spline Twist

The primary device used for comparison in this summary is Sulzer Dental's existing Spline Cylinder and Spline Twist implants. All implant systems are manufactured in the same facility located in Carlsbad, California.

1. Intended Use:

The intended use of the Small Diameter Spline Twist implant is identical to the intended use of the predicate implants. Sulzer 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 freestanding single tooth replacement.

Sulzer Dental recommends the Small Diameter Spline Twist implant for use in the anterior mandible and the maxillary laterals for replacement of teeth in narrow interproximal areas and narrow ridges.

2. Description:

Spline Twist implants are available with a roughened surface or a selectively roughened surface. They are available in a 3.15mm diameter and lengths of 10, 11.5, 13, 15, and 18mm. All implants have a Spline anti-rotational feature and are fabricated from titanium alloy. The implants are all provided sterile.

3. Technological Characteristics:

The Spline Dental Implant line has been modified to include a 3.15mm diameter threaded implant. The threaded design includes self-tapping capabilities. The implant/abutment interface remains unchanged. There has been no change to the implant materials or to the implant/abutment interface.

4. Comparison Analysis:

The overall design of the Spline Twist implant is similar to the predicate implant. See **Table 1** below for a comparison of the Spline Twist implant and the predicate device.

Table 1: Summary of Comparison

Feature	Small Diameter Spline Twist Implant	Predicate Device K944327 & K946311	Predicate Device K962106
Implant body geometry	Tapered, Self-Tapping Screw	Cylinder	Self-Tapping Screw Type
Implant Lengths	10, 11.5, 13, 15 & 18mm	8, 10, 13, 15 & 18mm	8, 10, 13, 15 & 18mm
Implant Body Diameter	3.15mm	3.25mm	3.75mm & 5.0mm
Implant Material	Titanium alloy	Same	Same
Implant Surface	Roughened	HA coated TPS coated	Roughened
Implant/Abutment Interface	Spline tine anti-rotational interface	Same	Same
Abutment Options	Fixed, Preangled, Shouldered, Overdenture & Gold copings	Same	Same
Manufacturing Site	Carlsbad, CA.	Same	Same
Packaging	Vial inside PETG tray sealed with Tyvek lid	Same	Same
Sterile	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Mr. Foster Boop
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K012055
Trade/Device Name: 3.25mm Spline Twist Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Dental Implant
Regulatory Class: Class III
Product Code: DZE
Dated: June 29, 2001
Received: July 2, 2001

Dear Mr. Boop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

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): K012055

Device Name: 3.15mm Spline Twist Implant

Indications for Use:

Sulzer 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. The 3.15mm implant is recommended for the anterior mandible and the maxillary laterals for replacement of teeth in narrow interproximal areas and narrow ridges.

(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 K012055