

ADMINISTRATIVE INFORMATION

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DEVICE NAME

Classification Name: Endosseous dental implant
Trade/Proprietary Name: Bicortical® Screw
Common Name: Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Oraltronics is registered with FDA under Establishment Registration Number 8010705.

DEVICE CLASSIFICATION

Endosseous dental implants have been classified by FDA as Class III devices under a final order published in the Federal Register of August 12, 1987, as shown in 21 CFR 872.3640. The device is reviewed by the Dental Products Panel, and the Product Code for the device is DZE.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Bicortical Screw complies include American Society for Testing and Materials (ASTM) designation F67 (Standard Specification for Unalloyed Titanium for Surgical Implant Applications), European Norm EN 552 on Irradiation Sterilization and ISO 11137 (Sterilization of Health Care Products - Radiation Sterilization). The Bicortical Screw carries the CE Mark, conforming to the European Medical Device Directive, 93/42/EWG, and it conforms to ISO 9001 on quality systems and to EN 46001, which relates ISO 9001 to medical devices.

PACKAGING/LABELING/PRODUCT INFORMATION

Bicortical Screw implants are packaged in a radiation sterilizable package consisting of three units. The first is an inner glass vial which is closed by means of a cap that holds the coronal portion of the implant, protecting it from contact with the vial during shipping and handling and facilitating delivery to the surgical site. This implant and vial unit is contained in a thermoformed plastic tray sealed with a Tyvek lid on which the primary product label is placed. The sealed tray is contained in a shelf package of paper cardstock that also contains the package insert/instructions for use. Sterilization is accomplished by means of Co⁶⁰ gamma irradiation at a dose of 25 kG (2.5 Mrad) minimum. Sterilization is validated by the bioburden method, using European Norm EN 552 on Irradiation Sterilization and ISO 11137 (Sterilization of Health Care Products - Radiation Sterilization). The sterility assurance level (SAL) that Oraltronics intends to meet for the Bicortical Screw is 10⁻⁶. The device is not represented to be "pyrogen free." Instruments are packaged non-sterile in plastic bags.

INTENDED USE

The Bicortical Screw is intended for surgical placement in edentulous anterior regions of the maxillary and/or mandibular arch to support crowns, bridges, or overdentures. In many cases the Bicortical Screw is inserted immediately after extraction.

DEVICE DESCRIPTION

Design Characteristics

Implants

The Bicortical Screw is a self-tapping, single-stage titanium implant that enjoys maximum primary support in the bone, i.e., bicortical support. The high degree of initial stabilization on

insertion ensures undisturbed healing for this free-standing implant. The implant site is prepared with a small diameter pilot bur and the screw implant cuts its own thread configuration, leaving only a very small wound. The implant is intended for sale in the United States with a square head and round head in two thread diameters each (3.5 mm and 4.5 mm major diameter). The square head version is bendable at the head whereas the round head version is not bendable.

Instrumentation

The complete set of surgical instrumentation was purposely kept small for easy handling. It consists of a special bur for preparing the alveolar ridge, two burs for preparing the bone for implant insertion, a curette and a series of elevators:

The Crestotom® is used when necessary to prepare the alveolar ridge for implantation. It is a side milling bur with a shape that offers simplicity and stability during osteoplasty.

The pilot bur of 1.2 mm diameter is usually sufficient for insertion of the Bicortical Screws of 3.5 mm diameter in D-3 and D-4 bone quality.

The twist drill, graduated, 2.0 mm diameter, is used for D-1 and D-2 bone quality and is sufficient to prepare the complete shaft diameter of the Bicortical Screw.

Other components include:

Graduated depth gauge corresponding with the implant diameter, to test the bone preparation in diameter and depth

Finger key

Extension for finger key, for application with elongated neighboring teeth and in small interdental spaces, to be mounted on the finger key of cardan joint key for implant insertion

Cardan joint key

Post bending pliers (square head only) opening at the front tip corresponding with the implant post, for adjusting the implant in small interproximal spaces

Post holding instrument for bending procedure (square head only) to be placed over the implant post for intraoral adjustment, attaching for support at the end of the round neck, keeping the implant neck in place during bending procedure and avoiding transfer of bending movements into bone

OP-tray, tray only

Biocortical-Kit (for square head)

Consisting of:

- OP-tray
- Pilot burs
- Twist drills
- Depth gauge
- Finger key
- Extension for finger key
- Post bending pliers
- Post holding instrument for bending procedure
- Cardan joint key
- 6 x transfer posts for square head
- 6 x model caps for square head
- x-ray guide 1:1, 26
- x-ray memory
- 12 Bicortical Screw implants with square head

Biocortical-Kit (for round head)

- OP-tray
- Pilot burs
- Twist drills
- Depth gauge
- Finger key
- Extension for finger key
- Cardan joint key
- 6 x transfer posts for round head
- 6 x model caps for round head
- x-ray guide 1:1, 26
- x-ray memory
- 12 Bicortical Screw implants with round head

Prosthetic parts and accessories include:

Impression caps

Modeling cap for model transfer, acrylic burnout wax-up cap

Transfer posts for square headed and round headed implants

Material Composition

Bicortical Screw implants are made from commercially pure titanium that meets ASTM specification F67 (Standard Specification for Unalloyed Titanium for Surgical Implant Applications), Grade 2. The use of titanium is widespread in commercially distributed, permanently implanted medical devices and the materials are widely considered to be biocompatible. Titanium is often used as a negative control in biocompatibility testing.

Animal Testing

A 31 month primate study by Sarnachiaro, et. al., showed that the interface between bone and the Bicortical Screw is fully osseointegrated, with no evidence of a fibrous tissue layer around the implants.

Clinical Studies

Results of retrospective analysis of consecutive patients from two centers treated between 1984 and 1997 are summarized below. Consecutive patients treated with 3.5 mm or 4.5 mm Bicortical Screws in the anterior were included in the analysis. Total numbers of patients, by gender, and total implants are shown for each center in Table I.

Table I
Demographic Information

	Center		Total
	A	B	
Male	64	61	125
Female	84	67	151
Total Patients	148	128	276
Implants	247	312	559

Criteria for success: Lack of mobility of free-standing implants was included as a criterion for single-tooth restorations and for initial integration, but was not used for implants in multi-unit prostheses after restoration. Patient care precluded removal of restorations to examine mobility. However, the usual criteria of freedom from pain, generalized radiolucency or uncontrolled bone loss were used.

Kaplan-Meier survival analysis showed that cumulative survival of Bicortical Screws after five years is 93.9 percent in one center and 97.9 percent in the other.

Literature on histopathology of implants removed from two patients due to trauma (one implant) and death (six implants) shows that histological evidence of osseointegration is present. Compact bone was observed around the screw with no evidence of connective tissue. Good bone contact, with no connective tissue, was observed in the margin and basal cortical bone of implants that had been in place for nearly ten years, illustrating the principle of bicortical support for this implant

design. One implant of the six lacked marginal bone support, but had apical apposition of bone. This examination included the observation of bone remodeling in cortical bone and evidence of microfracture and repair in cancellous bone.

EQUIVALENCE TO MARKETED PRODUCT

Oraltronics submits the following information to demonstrate that the Bicortical Screw Implant System is substantially equivalent in indications and design principles to the following predicate devices: Park Dental Research Corp. Pin Implant, a preamendments device that is marketed in the United States, and the Sendax MDI™ (K972351) and the Brånemark Fixture (K820013, K841551, K925764, K925765, K934825), implant systems that have been cleared for marketing in the United States.

Intended Uses

The indications for use for the Bicortical Screw and the predicate devices are substantially the same. All are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The major indications for the Bicortical Screw are in the anterior and presinus region of the upper jaw and in the interforaminal region of the lower jaw.

Design and Materials

The design and functional characteristics of the Bicortical Screw, the Pin Implant and the Sendax MDI are the same. They are narrow root-form, screw-type, titanium implants intended for support of prosthetic tooth restorations. The Brånemark Fixture has a slightly wider minor diameter (3.0 mm vs 2.25 mm), but is made from a weaker material. The Bicortical Screw is made from CP titanium, Grade 2, while the Brånemark Fixture is made from CP titanium, Grade 1. The Pin Implant is made from CP titanium (grade not known) and the Sendax MDI is made from Ti-6Al-4V alloy.

Mechanical Testing of Bicortical Screw

In order to compare the strength of the Bicortical Screw with that of the Pin Implant, static compression bending tests and bending fatigue tests were conducted. Bicortical Screws and Pin Implants were bent 15° to simulate the maximum correction that would be used with the square head Bicortical Screw during clinical use. Tests were done by applying a compression load 30° off the implant axis in order to simulate an extreme condition, more severe than would be expected clinically. Static tests were done to simulate a single extreme overload condition and dynamic tests were conducted to provide fatigue curves. Fatigue testing was done at 15 Hz in 37°C normal saline (0.9% NaCl), with runout defined as 5 million cycles. In the case of the Pin Implant, fatigue lives were so short at loads well below the fatigue limit of the Bicortical Screw that no attempt was made to reduce loads to the levels that might have resulted in runout.

The results of testing showed that the Bicortical Screw is nearly twice as strong in static bending compression as the Pin Implant. The 5 million cycle fatigue limit for the Bicortical Screw under these extreme conditions is more than twice that of the Pin Implant.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Bicortical Screw is substantially equivalent to the Pin Implant, the Sendax MDI and the Brånemark Fixture in the following respects:

	Subject Device	Predicate Devices		
	Bicortical® Screw Oraltronics	Pin Implant Park Dental Research Corp. (Pre- amendments)	Sendax MDI™ Sendax MDIC Management (K972351)	Brånemark Fixture Nobel Biocare (K820013, K841551, K925764, K925765, K934825)
INTENDED USE				
Surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients	YES	YES	YES	YES
DESIGN				
Solid body	YES	YES	YES	NO
Threaded	YES	YES	YES	YES
Single stage (transmucosal) design	YES	YES	YES	NO
Smooth transmucosal portion	YES	NO	YES	YES
Usable for immediate extraction sites	YES	YES	YES	NO
Thread major diameters, mm	3.5, 4.5	1.73		3.75, 4.0
Shank diameter or thread minor diameter, mm	2.25	~1.5	1.8	3.0
Lengths, mm	26, 30	45		7-20
MATERIAL				
Implant	CP Ti Grade 2	CP Ti	Ti-6Al-4V	CP Ti Grade 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1999

Oraltronics® Marketing-Und Vertriebs GmbH
C/O Mr. Floyd G. Larson
Pacific Materials and Interfaces
4329 Graydon Road
San Diego, California 92130

Re: K983120
Trade Name: Bicortical Screw
Regulatory Class: III
Product Code: DZE
Dated: December 15, 1999
Received: December 17, 1999

Dear Mr. Larson:

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

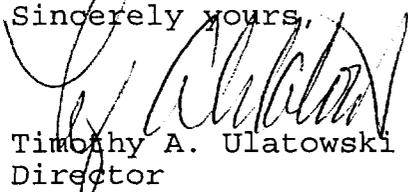
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Bicortical Screw Dental Implant System

Indications for Use:

The Bicortical Screw is intended for surgical placement in edentulous anterior regions of the maxillary and/or mandibular arch to support crowns, bridges, or overdentures. In many cases the Bicortical Screw is inserted immediately after extraction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Sarah Rimmer OR
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number KA8320

Over-The-Counter Use