K011574

ADMINISTRATIVE INFORMATION

SEP 2 8 2001

Manufacturer Name:	Universal Implant Systems, Inc. 1301 Ynez Place Coronado, CA 92118
Official Contact:	Robert F. Mansueto, D.D.S. Telephone (619) 435-6227 FAX (619) 435-4717
Representative/Consultant:	Floyd G. Larson PaxMed International 4329 Graydon Road San Diego, CA 92130 Telephone: (858) 792-1235 FAX: (858) 792-1236 E-mail: flarson@paxmed.com

DEVICE NAME

Classification Name:	Endosseous dental implant
Trade/Proprietary Name:	Uniplant Dental Implant System
Common Name:	Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Universal Implant Systems, Inc. is not yet registered with FDA.

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. Abutments to such implants are considered by FDA to be Class III devices inasmuch as they are used as accessories to or are used with endosseous dental implants. 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 Uniplant Dental Implant System complies include American Society for Testing and Materials (ASTM) designation F1472 (Standard Specification for Wrought Titanium 6Al-4V Alloy for Surgical Implant Applications (UNS R56400)) and ASTM F1609 (Standard Specification for Calcium Phosphate Coatings for Implantable Materials).

PACKAGING/LABELING/PRODUCT INFORMATION

Advertising material to be used for promotion of the Uniplant Dental Implant System will be consistent with the indications for use and other material shown herein.

Uniplant dental implants are packaged in a radiation sterilizable package consisting of an outer tamper evident container and an inner vial of glass or plastic. Sterilization is accomplished by means of Co^{60} gamma irradiation at a dose of 25 kGy (2.5 Mrad) minimum. Sterilization will be validated by the bioburden method. The sterility assurance level (SAL) that Universal Implant Systems intends to meet for the Uniplant dental implant is 10^{-6}. The device is not represented to be "pyrogen free." Abutments and instruments will be packaged either sterile in a system similar to the implant packaging or non-sterile in plastic bags.

INTENDED USE

The Uniplant Dental Implant System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

DEVICE DESCRIPTION

Design Characteristics

The Uniplant Dental Implant System is composed of a solid titanium alloy root-form implant and a solid conical abutment, with associated instruments. The implant is a screw-type, two-stage design, incorporating a titanium cover screw that seals the internal bore of the implant from the physiologic environment during healing. The implant is available in three diameters (3.4, 4.1 and 5.1 mm) and three implanted lengths (10 mm, 12 mm and 14 mm). The system includes surgical instruments such as drills, insertion modules and try-ins.

The system includes a solid conical abutment that is intended to be attached to the implant by engaging the threaded shaft of the abutment in the internal threaded bore of the implant. The abutment includes a cylindrical transmucosal portion and a tapered, grooved coronal portion, with an internal hex socket at the coronal end to facilitate attachment to the implant. A prosthesis may be fabricated by means of standard crown and bridge techniques for attachment to the abutment.

Material Composition

Implants and abutments for the Uniplant Dental Implant System are made from titanium-aluminum-vanadium alloy that meets ASTM designation F1472 (Standard Specification for Wrought Titanium -6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)). Uniplant implants have a smooth machined collar of 1.0 mm height and from that point to the apex are coated with a layer of plasma-sprayed hydroxyapatite (HA) to facilitate attachment of bone. An alternative surface treatment for the Uniplant implant is a resorbable blast media (RBM) treatment, in which acid soluble grit (hydroxyapatite) is used to roughen the surface in order to facilitate bone attachment. The surface is then treated with acid to remove any residual

any residual grit particles. The use of titanium, titanium alloy and HA coatings 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.

EQUIVALENCE TO MARKETED PRODUCT

Universal Implant Systems, Inc. submits the following information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Uniplant Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: "O" Company Threaded Implants and Fixed C&B Abutment (K923889, K950066, K961665, K973926), the Steri-Oss Replace HA-Coated Implant (K962845), and the Simpler Implant System (K974401, K974402, K974856, K974857).

Intended Uses

The indications for use for the Uniplant Dental Implant System 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.

Design and Materials

The design and functional characteristics of the Uniplant Dental Implant System and the "O" Company Threaded Implant are similar in their use of a root-form threaded design. The threads are intended to provide macroretention in bone and to increase the surface area for bone attachment relative to a smooth design. The threads of the Steri-Oss Replace implant and the Simpler threaded implant serve a similar function. The "O" Company Implant and Fixed C&B Abutment shares with the Uniplant Dental Implant System the method of attaching the abutment to the implant using a threaded abutment shaft. The Uniplant implant shares the use of Ti-6Al-4V with numerous marketed implants. It shares the use of an HA coating with the "O" Company Threaded Implant, the Steri-Oss Replace HA-Coated Implant, the Simpler HA-coated cylinder implant and numerous other marketed implants.

Hydroxyapatite Coating Characteristics

The characteristics of the HA coating used on the Uniplant Dental Implant System are shown in vendor master files. The Uniplant Dental Implant System HA coating has crystallinity, purity and mechanical properties at least as high as those of the coatings on currently marketed devices and at least as high as the suggestions of the FDA Guidance Document.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The Uniplant Dental Implant System is substantially equivalent to the "O" Company Threaded Implants and Fixed C&B Abutment, the Steri-Oss Replace HA-Coated Implant, and the Simpler Implant System in the following respects:

	Subject Device	Predicate Devices		
	Uniplant Dental Implant System	"O" Company Threaded Implants (K923889, K950066, K961665, K973926)	Steri-Oss Replace HA-Coated Implant (K962845)	Simpler Implant System (K974401, K974402, K974856, K974857)
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				
Body shape	cylindrical	cylindrical	tapered	cylindrical
Surface design	threaded	threaded	threaded	threaded or push-in
Single-stage or two-stage design	two-stage	two-stage	two-stage	single-stage or two-stage
Method of abutment attachment to implant	threaded connection	threaded connection	screw	threaded connection, screw, cement
Available diameters, mm	3.4, 4.1, 5.1	3.25, 4.0	6.0, 5.0, 4.3	3.25, 4.0
Available lengths, mm	10, 12, 14	8, 10, 12, 14, 16	10, 13, 16	8, 10, 13, 15
Solid abutment for cemented restorations	YES	YES	YES	YES
MATERIALS				
Implant body	Ti-6Al-4V	CP Ti	CP Ti	Ti-6Al-4V
Abutment	Ti-6Al-4V	Ti-6Al-4V	Ti alloy	Ti-6Al-4V
Surface characteristics / coating	RBM or HA	Machined or HA	HA	Grit blasted or HA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Universal Implant Systems, Incorporated
C/O Mr. Floyd G. Larson
Consultant
Paxmed International
4329 Graydon Road
San Diego, California 92130

Re: K011574
Trade/Device Name: Uniplant Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: May 18, 2001
Received: May 22, 2001

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 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). 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 requirements, 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) 594-4692. 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" (21CFR 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 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

K011574

Device Name: Uniplant Dental Implant System

Indications for Use:

Intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

MEA for NSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011574