510(K) Summary

JUN 0 5 2014

Submitter
T Strong, Inc.
Han Chang Woo
181-4 Uijeon-ri, Jinyeong-eup,
Gimhae-si, Gyeongnam
621-801, Republic of Korea
Phone: +82-55-342-1771
Fax: +82-55-342-1775

Official Correspondent
Kodent, Inc.
Susan Park
325 N. Puente st. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-01116

Date prepared: 9/17/2013

Device Information
Trade Name: U fit Dental Implant System
Common Name: Endosseous dental implant
Classification Name: Implant, Endosseous, Root-Form
Product code: DZE
Subsequent Product Code: NHA
Device Class: Class II
Regulation number: 21 CFR 872.3640

General Description

The U fit Implant System is a dental implant system made of Titanium-6Al-4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for lading after a conventional healing period.

The implants may be used to replace one or more missing teeth. The systems are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of these systems have been treated with RBM (Resorbable Blasted Media).

The Fixture diameters are 3.8, 3.9, 4.0, 4.1, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 mm and lengths are 7, 8.5, 10, 11.5, 13, 14.5 mm in this system.

The contained various abutments and accessories in the system are cover screw, abutment screw, healing abutment, solid abutment, transfer abutment, milling abutment, Temporary Abutment, protect cap, solid impression coping, solid lab analog, impression coping/pick-up, impression coping/transfer, and fixture lab analog.

The material of abutments and accessories are Ti-6Al-4V ELI(ASTM F-136), POM-C and stainless steel. The abutment diameters are 4.0, 4.1, 4.4, 4.5, 4.8, 5.0, 5.3, 5.5, 5.8, 6.0, 6.3, 6.5, 6.8, 7.0, 7.3, 7.8 and Heights are 4.0, 5.5, 7.0, 9.0.

The implants are supplied sterile and the abutments and accessories are provided non-sterile. The abutments and accessories should be sterilized before use.

Indications for Use

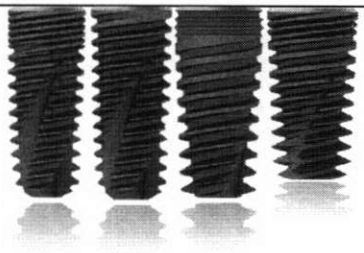
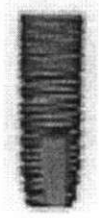
The U fit Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed

bridgework. The U fit Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

Predicate Device Information
The subject device is substantially equivalent to the following predicate device:

- US/SS/GS System manufactured by OSSETEM Co., Ltd. (K073247)
- Implantium Abutment manufactured by Dentium Co., Ltd. (K052823)

Comparison Chart
1) Fixtures

	Subject device	Predicate device
Device name	U fit Dental Implant System	US/SS/GS System
510(k) number	NA	K073247
Manufacturer	T Strong, Inc.	OSSETEM Co., Ltd.
Intended use	Identical to the predicate	The US/SS/GS System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The U fit Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading.
Material	Ti-6Al-4V ELI ASTM F136	Ti-6Al-4V ELI ASTM F136
Design		
Fixture Type	Submerged	Submerged
Implant diameter	3.8, 3.9, 4.0, 4.1, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0 mm	3.3 - 6.0 mm
Implant length	7, 8.5, 10, 11.5, 13, 14.5 mm	7 - 18 mm
Components	Various abutments and accessories	Various abutments and components
Surface treatment	RBM	RBM

Gamma sterilized	Yes	Yes
Product Code	DZE	DZE

2) Abutments

	Subject Device	**Predicate Device**
Device Name	U fit Dental Implant System	IMPLANTIUM ABUTMENTS
510k #	NA	K052823
Manufacturer	T Strong, Inc.	Dentium, Inc.
Product Code	NHA	NHA
Cover Screw		
Design		
Intended Use	To provide sealing effect for fixture	To provide sealing effect for fixture
Material	Ti-6Al-4V ELI Gr.23	Ti-6Al-4V ELI Gr.23
Sterilization	Steam Sterilization by user	Steam Sterilization by user
Abutment Screw		
Design		
Intended Use	To connect abutment to fixture	To connect the abutment to the fixture
Material	Ti-6Al-4V ELI, ASTM F136	Ti-6Al-4V ELI, ASTM F136
Sterilization	Steam Sterilization by user	Steam Sterilization by user
Healing Abutment		
Design		
Intended Use	To help the soft tissue of gum naturally formed	To help the soft tissue of gum naturally formed
Material	Ti-6Al-4V ELI Gr.23	Ti-6Al-4V Eli, Gr. 23
Sterilization	Steam Sterilization by user	Gamma Sterilization
Solid Abutment		
Design		

Intended Use	Cement retained restoration	Cement retained restoration
Material	Ti-6Al-4V ELI Gr.23	CP Ti Gr.4
Sterilization	Steam Sterilization by user	Steam Sterilization by user
Transfer Abutment		
Design		
Intended Use	Cement retained restoration	Cement retained restoration
Material	Ti-6Al-4V ELI Gr.23	CP Ti Gr4.
Sterilization	Steam Sterilization by user	Steam Sterilization by user
Milling Abutment		
Design		
Intended Use	Cement retained restoration	Cement retained restoration
Material	Ti-6Al-4V ELI Gr.23	CP Ti Gr3. ASTM F67
Sterilization	Steam Sterilization by user	Steam Sterilization by user
Temporary Abutment		
Design		
Intended Use	To manufacture temporary prostheses	To manufacture temporary prostheses
Material	Ti-6Al-4V ELI Gr.23	CP Ti Gr.4
Sterilization	Steam Sterilization by user	Steam Sterilization by user

Comparison Analysis

The U fit Dental Implant System has a substantially equivalent intended use as the identified predicate. The U fit Dental Implant System is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium.

The U fit Dental Implant System is substantially equivalent in materials, indications and intended use, packaging, labeling, and performance to the predicate device currently marketed in the U.S.

The only differences between the subject device and the predicate are slight differences in fixture designs and diameters.

Any differences in technology characteristics are accompanied by information that demonstrated the device is safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate.

Non-Clinical Data

The manufacturing and development process for the U fit Dental Implant System is compliance with ISO 13485(Medical devices — Quality management systems — Requirements for regulatory purposes), ISO 14971(Medical devices — Application of risk management to medical devices), ISO 10993-1(Biological evaluation of medical devices), EN 980(Symbols for use in the labelling of medical devices), EN 1041(Information supplied by manufacturer of medical devices). Biocompatibility testing has been performed in accordance with ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO10993-10, ISO 10993-11, ASTM F67, ASTM F750-87, USP<88>, USP<151>, ISO 7405. Sterilization validating testing has been performed in accordance with ISO 11737-1 & ISO 11737-2 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization. Analysis of chemical and SEM images have been performed to verify that there is no residual after RBM treatment on the Fixture. Non-clinical testing consisted of performance of testing in accordance with the FDA guidance "Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The results of the non-clinical testing demonstrate that the U fit Dental Implant System is substantially equivalent to the predicate devices.

Conclusion

The U fit Dental Implant System constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. The risks of using the device as recommended pose no greater risks than other implant systems. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, U fit Dental Implant System and its predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

T Strong, Incorporated
C/O Ms. Susan Park
Kodent, Incorporated
325 N. Puente Street, Unit B
Brea, California 92821

Re: K132956
Trade/Device Name: U Fit Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 24, 2014
Received: April 24, 2014

Dear Ms. Park:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K132956

Device Name: U fit Dental Implant System

The U fit Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The U fit Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

Prescription Use ____X_____ AND/OR Over-The-Counter _____
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of 1

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