



Food and Drug Administration
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June 21, 2016

Dentis Co., Ltd.
c/o Ms. April Lee
Withus Group, Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K160213

Trade/Device Name: s-Clean Tapered II RBM Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: May 10, 2016
Received: May 16, 2016

Dear Ms. Lee:

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,

 Tina Kiang
-S

for Erin I. Keith, M.S.

Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

s-Clean Tapered II RBM Implant System

Indications for Use (Describe)

The s-Clean Tapered II RBM Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted Interforaminal placed implants.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary**Submitter**

Dentis Co., Ltd.
Sun Chul Shin
99, Seongseoseo-ro, Dalseo-gu
Daegu, 42718
South Korea
Phone: +82-53-583-2804
Fax: +82-53-583-2806

Official Correspondent

Withus Group Inc.
April Lee
2531 Pepperdale Drive
Rowland Heights, CA 91748 USA
Email: withus6664@gmail.com
Phone: 909-274-9971
Fax: 909-460-8122

Device Information

Trade Name: s-Clean Tapered II RBM Implant System
Common Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant
Primary Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 6/20/2016

Description

The s-Clean Tapered II RBM Implant System is a dental implant made of titanium metal (Titanium grade 4) intended to be surgically placed in the bone of the upper or lower jaw arches. This implant system has internal hex connection, 1.5° tapered body, bone level and submerged type that are similar to other commercial available products based on the intended use, technology used, the claims, the material composition employed and performance characteristics. The surface of the fixture has been treated with RBM (Resorbable Blasted media).

The s-Clean Tapered II RBM Implant System diameter and lengths are below:

- Diameter Ø 3.7 with lengths of 7mm, 8mm, 10mm, 12mm and 14 mm
- Diameter Ø 4.1 with lengths of 7mm, 8mm, 10mm, 12mm and 14 mm
- Diameter Ø 4.3 with lengths of 7mm, 8mm, 10mm, 12mm and 14 mm
- Diameter Ø 4.8 with lengths of 7mm, 8mm, 10mm, 12mm and 14 mm

The packaging has composed of fixture with cover screw. The fixtures are supplied sterile by gamma sterilization. The fixtures are provided as set-packing with the cover screw. The purpose of this submission is to add new fixtures.

The subject device is compatible with the following abutments:

K number	Compatible Abutments
K073486	s-Clean Healing Abutment, s-Clean Free-Healing abutment, s-Clean Couple Abutment, s-Clean Sole Abutment, s-Clean Sub Octa Abutment, s-Clean O-ring Abutment
K082843	s-Clean Angled Abutment, s-Clean Healing Abutment
K111364	s-Clean Sole Abutment, s-Clean Hex Abutment, s-Clean Temporary Abutment, s-Clean O-Ring Abutment, s-Clean Free Abutment, s-Clean Sub-Octa Abutment, s-Clean FreeMill Abutment, s-Clean MOA Abutment
K150344	MU Solid Abutment, MU Couple Abutment, MU Angled Abutment

Indication for Use

The s-Clean Tapered II RBM Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted Interforaminal placed implants.

Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate devices:

- K150344 Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K074386 Dentis Dental Implant System manufactured by Dentis Co., Ltd.

Division	Subject Device	Primary Predicate	Reference Predicate
Device Name	s-Clean Tapered II RBM Implant System	Dentis Dental Implant System	Dentis Dental Implant System
510(k)	N/A	K150344	K073486
Manufacturer	DENTIS CO., LTD.	DENTIS CO., LTD.	DENTIS CO., LTD.
Indication for use	The s-Clean Tapered II RBM Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single	The Dentis Dental Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical	The Dentis 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. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This

	stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted Interforaminal placed implants.	process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted interforaminal placed implants.	system is intended for delayed loading.
Fixture Material	CP Titanium Gr.4	CP Titanium Gr.4	CP Titanium Gr.4
Fixture Diameter	Ø 3.7, Ø 4.1, Ø 4.3, Ø 4.8mm	Ø 3.7, Ø 4.1, Ø 4.3, Ø 4.8m	Ø 3.5, Ø 3.7, Ø 4.1, Ø 4.3, Ø 4.8, Ø 5.1, Ø 5.5, Ø 6.0, Ø 6.5, Ø 7.0mm
Fixture Length	7, 8, 10, 12, 14 mm	7, 8, 10, 12, 14 mm	7, 8, 9, 10, 12, 14 mm
Design (Fixture Type)	 <ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture -Bone level, Tapered body - 4 sided cutting edge with self-tapping 	 <ul style="list-style-type: none"> -Internal Hex-Connected -Submerged Fixture -Bone level, Tapered body - 4 sided cutting edge with self-tapping 	 <ul style="list-style-type: none"> -Internal Hex-Connected -Submerged Fixture -Bone level, Tapered body - 4 sided cutting edge with self-tapping
Surface Treatment	RBM	RBM	RBM
Gamma Sterilized	Yes	Yes	Yes
Product Code	DZE	DZE, NHA	DZE, NHA

Substantial Equivalence Discussion

The s-Clean Tapered II RBM Implant System has a substantially equivalent intended use as the identified predicates. The subject device 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 subject and predicate devices are similar in indication for use, material, connection structure, packaging, function, using abutments, performance, design, technology and dimensions. The s-Clean Tapered II RBM Implant System is compatible with abutment in s-Clean part of the Dentis Dental Implant System.

This subject device is same with RBM surface treatment of Dentis Dental Implant System of the K150344 that have had same material, manufacturing process, packaging, sterilization condition and surface characteristic.

The differences between the subject device and predicate devices are only the fixture's shape. Thread design of the coronal aspect of the threaded fixture body has changed from the predicate.

Non-Clinical Test Data

No additional test was performed for this subject system.

Fatigue testing was considered according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the Dentis Dental Implant System (K150344) in s-Clean tapered Fixture and the angled abutment in support. Therefore, Submitted fatigue test report can be used as a proof of s-Clean Tapered II RBM Implant System.

Gamma Sterilization Validation Test was referenced in reference predicate, K073486.

Shelf life Validation Test was referenced in reference predicate, K073486.

The testing has been performed to evaluate the substantial equivalence in the characteristics compared to the predicate device. The result of the above tests have met the criteria of the standard, and proved the substantial equivalence with the predicate device.

Summary of clinical testing

No clinical testing was performed for this submission.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Dentis Co., Ltd. Concludes that the s-Clean Tapered II RBM Implant System is substantially equivalent to the predicate devices as described herein