



Food and Drug Administration
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April 8, 2016

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

Re: K153639

Trade/Device Name: OneQ-SL s-Clean Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 3, 2016
Received: March 11, 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" (21 CFR 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,

 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)
K153639

Device Name

OneQ-SL s-Clean Implant System

Indications for Use (Describe)

The OneQ-SL s-Clean 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. This system is intended for delayed loading.

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

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Device Information

Trade Name: OneQ-SL s-Clean Implant System
Common Name: Endosseous Dental Implant
Classification Name: Endosseous dental implant
Product Code: DZE
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 4/7/2016

Description

The OneQ-SL s-Clean Implant System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. This implant system has internal hex connection, tapered with straight 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. This implant system is supplied by gamma sterilized that is same with almost all dental implant. The OneQ-SL s-Clean Implant system is substantially equivalent in connection structure, similar design, function and intended use to the Dentis dental implant system (K073486) of DENTIS Co., Ltd., and Dentis dental implant system(K150344) of DENTIS Co., Ltd. The difference between the subject and the predicate device are slightly different shape and surface treatment. This subject device is compatible with the abutments of K073486, K082843, K111364 and K150344.

The OneQ-SL s-Clean Implant system diameter and lengths are below:

- The OneQ-SL s-Clean Fixtures
Internal Hex-connected, Bone level, submerged fixture, Tapered & Straight body
Implant Fixture Dimension:

Division	Platform Diameters (Fixture Diameters)	Body Diameters	Lengths
Regular	Ø3.7	Ø3.5	7, 8, 10 ,12, 14 mm
	Ø3.9	Ø3.6	
	Ø4.2	Ø3.7	
	Ø4.7	Ø4.2	
	Ø5.2	Ø4.7	
Wide	Ø6.0	Ø4.8	7, 8, 10 ,12 mm



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	Ø7.0	Ø5.8	
	Ø8.0	Ø6.8	

The fixture and cover screw are made of CP Titanium Grade 4. The surface is treated by Sand –blasting (Large grit) and acid etching method (SLA). This system only contains the implant bodies with cover screw and are provided as set-packing. The purpose of this submission is to add new fixtures.

Indications for Use

The OneQ-SL s-Clean 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. This system is intended for delayed loading.

Predicate Devices & Comparison

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

- K150344/K073486, Dentis Dental Implant System manufactured by Dentis Co., Ltd.
- K142313, OneQ-SL Implant System manufactured by Dentis. Co., Ltd.
- K063216, Rescue Internal Dental Implant System by Megagen Co., Ltd.

Division	Subject Device	Predicate		Predicate	Predicate
Device Name	OneQ-SL s-Clean Implant System	Dentis Dental Implant System	Dentis Dental Implant System	OneQ-SL Implant System	Rescue Internal Dental Implant System
510(k) Number	N/A	K073486	K150344	K142313	K063216
Manufacturer	DENTIS CO., LTD.	DENTIS CO., LTD.	DENTIS CO., LTD.	DENTIS CO., LTD.	MEGAGEN Co., Ltd.
Material	CP Titanium Gr.4	CP Titanium Gr.4	CP Titanium Gr.4	CP Titanium Gr. 4	CP Titanium Gr. 4
Design (Fixture Type)	 <ul style="list-style-type: none"> - Internal Hex-connected - Submerged Fixture - Bone level - Tapered & straight body - 3 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 	 <ul style="list-style-type: none"> - Internal Octa-connected - Non Submerged Fixture - Tapered & straight body - 3 sided cutting edge with self-tapping 	 <ul style="list-style-type: none"> -Internal Hex-connected -Submerged Fixture -Bone level, Straight body -4 sided cutting edge and self-tapping
Fixture Diameter	Regular: \varnothing 3.7, \varnothing 3.9, \varnothing 4.2, \varnothing 4.7, \varnothing 5.2 Wide: \varnothing 6.0, \varnothing 7.0, \varnothing 8.0	\varnothing 3.5, \varnothing 3.7, \varnothing 4.1, \varnothing 4.3, \varnothing 4.8, \varnothing 5.1, \varnothing 5.5, \varnothing 6.0, \varnothing 6.5, \varnothing 7.0	\varnothing 3.7, \varnothing 4.1, \varnothing 4.3, \varnothing 4.8	Regular(4.8 Platform): \varnothing 3.7, \varnothing 4.2, \varnothing 4.7, \varnothing 5.2 Wide(6.5 Platform): \varnothing 4.7, \varnothing 5.2, \varnothing 6.0, \varnothing 7.0	\varnothing 6.0, \varnothing 6.5, \varnothing 7.0, \varnothing 8.0
Fixture Length	Regular: 7, 8, 10, 12, 14 mm Wide: 7, 8, 10, 12 mm	7, 8, 9, 10, 12, 14 mm	7, 8, 10, 12, 14 mm	Regular: 7, 8, 10, 12, 14mm Wide(\varnothing 4.7, \varnothing 5.2): 7, 8, 10, 12, 14mm	7.0~12.5mm



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				Wide(Ø6.0, Ø7.0): 7, 8, 10, 12mm	
Indication for use	<p>The OneQ-SL s-Clean 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. This system is intended for delayed loading.</p>	<p>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 system is intended for delayed loading.</p>	<p>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 process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splinted interforminal placed implants.</p>	<p>The OneQ-SL 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 intended for delayed loading.</p>	<p>The Rescue Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations(Crown, bridges and overdentures) in partially or fully edentulous individuals. These implants are intended to be used where smaller implants have failed.</p>
Surface Treatment	SLA	RBM	RBM	SLA	RBM
Gamma Sterilized	Yes	Yes	Yes	Yes	YES
Product Code	DZE	DZE, NHA	DZE, NHA	DZE	DZE, NHA

Substantial Equivalence Discussion

The OneQ-SL s-Clean 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 OneQ-SL s-Clean Implant system is compatible with abutment in s-Clean part of the Dentis Dental Implant System. This subject device is same with SLA surface treatment of OneQ-SL Implant System of the K142313 that have had same material, manufacturing process, packaging, sterilization condition and surface characteristic.

The differences between the subject device and predicate devices are fixture's diameters and similar thread shape.

The subject device platform diameters are $\varnothing 3.7$, $\varnothing 3.9$, $\varnothing 4.2$, $\varnothing 4.7$, $\varnothing 5.2$, $\varnothing 6.0$, $\varnothing 7.0$ and $\varnothing 8.0$.

The predicate device platform diameters are $\varnothing 3.5$, $\varnothing 3.7$, $\varnothing 4.1$, $\varnothing 4.3$, $\varnothing 4.8$, $\varnothing 5.1$, $\varnothing 5.5$, $\varnothing 6.0$, $\varnothing 6.5$, and $\varnothing 7.0$ (K073486).

The predicate device platform diameters are $\varnothing 3.7$, $\varnothing 4.2$, $\varnothing 4.7$, $\varnothing 5.2$, $\varnothing 6.0$ and $\varnothing 7.0$. (K142313).

The subject device's thread is composed of double thread of acme thread types and predicate device (K150344)'s threads are composed of micro thread and macro thread of buttress thread type.

Reference predicate K063216 supports the substantial equivalence of the subject device's wide fixture with a diameter of 8.0mm.

This implant system has been subjected to several performance and product validations prior to release. Nonclinical tests, including biocompatibility have been performed to ensure the device comply with the applicable International and US regulations.

Differences in technological characteristics do not raise different questions compared to the predicate devices.

Non-Clinical Test Data

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Gamma Sterilization Validation Test performed in accordance with ISO11137-1
- Shelf life Validation Test performed in accordance with ISO 11607-1, -2, ASTM F1980-07
- Biocompatibility tests performed in accordance with ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10 and ISO 10993-11.

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 OneQ-SL c-Clean implant system.

Those tests have been performed to evaluate the substantial equivalence in the surface characteristics compared to the predicate device. The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device.



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The results of the non-clinical testing demonstrate that the subject device is substantially equivalent to 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 *OneQ-SL s-Clean Implant System* is substantially equivalent to the predicate devices as described herein.