DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 27, 2017

Dentis Co., Ltd.
% April Lee
Consultant
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K170220
Trade/Device Name: OneQ-SL s-Clean Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: April 19, 2017
Received: April 19, 2017

Dear April 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indication for Use

Device Name: OneQ-SL s-Clean Implant System

Indication 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.

Prescription Use ____X_____

(Part 21 CFR 801 Subpart D)

510(K) Summary

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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: 04/13/2017

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 sterile.
The OneQ-SL s-Clean Implant system is substantially equivalent in connection structure, similar design, function and intended use to the predicate device, OneQ-SL s-Clean Implant System (K153639). 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	

The fixture is made of Ti-6Al-4V ELI and Pure Titanium Grade 4. The Cover screw was cleared in K073486. 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.

Indication 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:

- K153639, OneQ-SL s-Clean Implant System by Dentis Co., Ltd.
- K161244, s-Clean OneQ-SL Narrow System by Dentis Co., Ltd.
- K150344, Dentis Dental Implant System by Dentis Co., Ltd.

Division	Subject Device	Primary Predicate	Reference Predicate	
Device Name	OneQ-SL s-Clean Implant System	OneQ-SL s-Clean Implant System	s-Clean OneQ-SL Narrow Implant System	Dentis Dental Implant System
510(k) Number	N/A	K153639	K161244	K150344
Manufacturer	DENTIS CO., LTD.	DENTIS CO., LTD.	DENTIS CO., LTD.	DENTIS CO., LTD.
Material	Ti-6Al-4V-ELI CP Titanium Gr.4	CP Titanium Gr.4	Ti-6Al-4V-ELI	CP Titanium Gr.4
Design (Fixture Type)	 • Internal Hex-connected • Submerged Fixture • Bone level • Tapered & straight body • 3 sided cutting edge with self-tapping	 • Internal Hex-connected • Submerged Fixture • Bone level • Tapered & straight body • 3 sided cutting edge with self-tapping	 • Internal double hex connection • Straight and tapered implant body • 3 sided cutting edge of bottom and bone level design	 • Internal Hex-Connected • Submerged Fixture • Bone level, Tapered body • 4 sided cutting edge with self-tapping
Fixture Diameter	Ø3.7, Ø3.9,	Ø3.7, Ø3.9, Ø4.2, Ø4.7, Ø5.2	Ø 3.0, Ø 3.3, Ø 3.7	Ø3.7, Ø4.1, Ø4.3, Ø4.8
Fixture Length	7, 8, 10 ,12, 14 mm	7, 8, 10 ,12, 14 mm	8, 10 ,12, 14 mm	7, 8, 10, 12, 14 mm
Surface Treatment	SLA	SLA	SLA	RBM
Gamma Sterilized	Yes	Yes	Yes	Yes
Product Code	DZE	DZE, NHA	DZE, NHA	DZE, NHA
Shelf Life	8 years	1 year	8 years	5 years

Indication 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.	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.	The s-Clean OneQ-SL Narrow Implant System (3.0, 3.3mm) may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, 2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or 3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.	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.

Substantial Equivalence Discussion

The subject device shares identical Indications for Use statement as the primary predicate device (K153639). The technological features of the subject device differ from the primary predicate in the following ways:

- Addition of 3.7mm and 3.9mm diameter of Implants made of Ti-6Al-4V (ELI)
- 8 years of Shelf Life

The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244) and dentis dental implant system (K153639), support substantial equivalence of the addition of 3.7mm and 3.9mm diameter of Implants with different material and shelf life.

Non-Clinical Test Data

Below tests were performed for predicate devices and leveraged for the subject device:

- Gamma Sterilization Validation Test according to ISO11137-1,- 2 referenced in K153639 and K161244
- Shelf life Validation Tests referenced in K153639 and K161244
  - Tensile Test according to ASTM D882
  - Seal Peeling Test according to ASTM F88
  - Burst Test according to ASTM F1140
  - Dye penetration Test according to ASTM F1929
  - Bubble Test according to ASTM F2096
- Fatigue Test according to ISO 14801:2007 referenced in K150344 and K153639
- Biocompatibility Test referenced in K161244
  - Cytotoxicity according to ISO10993-5
  - Sensitization according to ISO10993-10
  - Irritation according to ISO10993-10
  - Acute systemic toxicity according to ISO 10993-11
  - Implantation according to ISO 10993-6
  - Genotoxicity according to ISO 10993-3
  - Subchronic Toxicity according to ISO 10993-11 and ISO 10993-6
- Endotoxin Test according to USP <85> referenced in K161244

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.

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.