DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 7, 2016

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

Re: K161244
Trade/Device Name: s-Clean OneQ-SL Narrow Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 1, 2016
Received: November 7, 2016

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 yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161244

Device Name
s-Clean OneQ-SL Narrow Implant System

Indications for Use *(Describe)*
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.

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)

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510(K) Summary

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Device Information
Trade Name: s-Clean OneQ-SL Narrow Implant System
Common Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form
Product Code: DZE, NHA
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 11/29/2016

Indication for Use
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.

Device Description
The s-Clean OneQ-SL Narrow Implant System is used to replace missing teeth in various situations ranging from a single tooth loss to the complete loss of incisors teeth. This system is restricted to substitute the maxillary lateral incisors and mandibular incisors. It is one and two stage endosseous screw type implant with internal double hexagonal connection, intended for single use. The s-Clean OneQ-SL Narrow Implant System is a suitable treatment option when the possibility of placing a standard implants is limited due to physical conditions, where the horizontal space is limited by adjacent teeth and roots, or in situations with a narrow alveola ridge.

This system consists of the fixture, cover screw, various abutments and prostheses. Only the subject abutments can be used with the subject fixtures.

Fixture

This fixture design has straight and tapered implant body, 3 sided cutting edge of bottom, internal double hex connection and bone level implant. The Fixture diameters are 3.0 and 3.3 mm and the lengths are 10, 12 and 14mm.

This product is a dental implant which is placed in the maxillary and mandibular bone to support and maintain upper prostheses or denture. Fixture, the lower part of the main body, is made of Ti-6Al-4V ELI for Narrow type, and SLA (Sand-blasted, Large grit, Acid-etched surface) surface treated. Fixture and cover screw are provided sterile.

Abutment

The various abutments in this system include s-clean sole narrow abutment, healing cap, s-clean narrow temporary abutment, s-clean narrow O-ring abutment, s-clean narrow healing abutment, s-clean narrow gold UCLA abutment, and s-clean narrow CCM Abutment.

Item	Description	Dimension	Materials
s-Clean Sole Abutment (Narrow)	upper structure used to produce a dental prosthesis bridge for 2~3 or more teeth..	Ø 4.0 mm (D) x 9.4, 10.4, 10.9, 11.9, 12.4, 12.9, 13.4, 14.4, 14.9 and 15.9 mm (L)	Ti-6Al-4V ELI
Healing Cap	connected sole abutment after connection to sole abutment and contact to gingiva duration 15 days less to protect to tongue	Ø 4.6 mm (D) x 6, 7.5 and 9 mm (L)	Acetal
s-Clean Temporary Abutment (Narrow)	Arbitrarily shaped upper structure used to restore masticatory movement temporarily by using prosthesis made according to patient's condition	Ø 4.0 mm (D) x 12.5 and 13 mm (L)	Titanium Grade 4
s-Clean O-Ring Abutment (Narrow)	Ball type upper structure connects with the top of implant fixture to connect with over denture	Ø 3.5 mm (D) x 10 and 12 mm (L)	Ti-6Al-4V ELI
s-Clean Healing Abutment (Narrow)	Can be made emergence profile on gingiva for next connecting abutment and be used period 15 days from secondsurgery normally	Ø 4.0 mm (D) x 7.9, 8.4, 8.9, 9.4, 9.9, 10.4, 10.9 and 11.4 mm (L)	Titanium Grade 4
s-Clean Gold UCLA Abutment (Narrow)	Make castable abutment and is screw retained type	Ø 4.0 mm (D) x 14.5 and 15 mm (L)	Gold
s-Clean CCM Abutment (Narrow)	Make castable abutment and is screw retained type	Ø 4.0 mm (D) x 14.5 and 15 mm (L)	Co-Cr-Mo Alloy
s-Clean Abutment Screw	Connection body to connect abutment to fixture	Ø 2.03 mm (D) x 9 mm (L)	Ti-6Al-4V ELI

The Healing Abutments are provided sterile and other abutments are provided non-sterile. The abutments should be sterilized before use (End user sterilization).

The temporary abutments, CCM abutments and UCLA abutments are not intended to be cast at angulation or placed to provide angular correction.

Principle of Operation

This product is a dental implant to implant in the jaw to maintain support for partial or full prosthetic restorations teeth or dentures when the loss of teeth as the fixture dental implant, the body (substructure) made titanium and was treated SLA surface.

Predicate Devices & Comparison

1) Fixtures

- K093321, BioHorizons Laser-Lok 3.0 Implant System
- K130462, Paltop Narrow Implant
- K150344, Dentis Dental Implant System
- K111364, Dentis HAPTITE Implant system

	Subject device	Primary Predicate	Reference Predicates		
Device name	s-Clean OneQ-SL Narrow Implant System	BioHorizons Laser-Lok 3.0 Implant System	Paltop Narrow Implant	Dentis Dental Implant System	Dentis HAPTITE Implant system
510(k) number	K161244	K093321	K130462	K150344	K111364
Manufacturer	Dentis Co., Ltd.	BioHorizons Implant Systems, Inc	Paltop Advanced Dental Solutions, Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	CP Titanium Grade 4	CP Titanium Grade 4
Design					
Design and technological features	Straight and tapered implant body, 3 sided cutting edge of bottom, internal double hex connection and bone level design.	Straight and tapered implant body, Laser-Lok collar, Parallel wall, Internal hex connection and bone level design.	Straight and tapered implant body, 3 sided cutting edge of bottom, internal hex connection and bone level design.	Tapered implant body, 4 sided cutting edge of bottom, internal hex connection and bone level design.	Tapered implant body, 4 sided cutting edge of bottom, internal hex connection and bone level design.
Fixture diameter(Ø)	3.0, 3.3 mm	3.0mm	3.25 mm	3.7, 4.1, 4.3, 4.8mm	3.7, 4.1, 4.3, 4.8, 5.5, 6.0, 6.5 and 7.0mm

Fixture length	10 ,12, 14 mm	10.5, 12, 15mm	10,11.5,13,16 mm	7, 8, 10 ,12, 14 mm	7, 8, 9, 10 ,12, 14 and 16mm
Indication for use	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.	BioHorizons Laser-Lok 3.0 Implants 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 Peltop Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	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.	The Dentis 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.
Surface treatment	SLA	RBM	SLA	RBM	HA Coating
Principle of	Conventional procedure	Conventional procedure	Conventional	Conventional procedure	Conventional

Operation			procedure		procedure
Anatomical Site	Oral cavity mandibles and maxillae	Oral cavity mandibles and maxillae	Oral cavity mandibles and maxillae	Oral cavity mandibles and maxillae	Oral cavity mandibles and maxillae
Gamma sterilized	Yes	Yes	Yes	Yes	Yes
Abutment	Straight only	Straight and angled	Straight and angled (20°)	Straight and angled (30°)	Straight and angled(25°)
Material Composition of Abutments	CP Titanium Grade 4, Ti-6Al-4V ELI, CCM Alloy, Acetal, Gold	Titanium Alloy	Titanium Alloy	CP Titanium Grade 4 Ti-6Al-4V ELI, CCM Alloy, Acetal	CP Titanium Grade 3 and 4 Ti-6Al-4V ELI, PEEK, Gold, Acetal
Surface Treatment of Abutments	None	None	None	None	None
Product Code	DZE, NHA	DZE	DZE, NHA	DZE, NHA	DZE, NHA

2) Abutments

- K150344, Dentis Dental Implant System
- K111364, Dentis HAPTITE Implant system
- K073486, Dentis Dental Implant System

Sole Abutment			
K number	K161244 (Subject)	K150344	K111364
Product Name	s-Clean Sole Abutment (Narrow)	-	s-Clean Sole Abutment
Intended Use	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 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.	The HAPTITE coating 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.
Materials	Ti-6Al-4V ELI / Non coating	-	Ti-6Al-4V ELI / Non coating
Dimension	Ø 4.0 mm (D) x 9.4, 10.4, 10.9, 11.9, 12.4, 12.9, 13.4, 14.4, 14.9, 15.9 mm (L)	-	Ø 4.5, 5.5, 6.5 mm (D) x 12.5, 13, 13.5, 14, 15, 16, 17mm (L) Ø 4.8, 6.0 mm(D) x 13.3, 14.3, 15.3, 16.3, 17.3 mm(L)
Healing Cap			
Product Name	Healing Cap	MU Healing Cap	Healing Cap
Materials	Acetal / Non coating	Ti-6Al-4V ELI / Non coating	Acetal / Non coating
Dimension	Ø 4.6 mm (D) x 6, 7.5, 9 mm (L)	Ø 5.4 mm (D) x 5 mm (L)	Ø 5.1, 5.8, 6.3, 6.8 mm (D) x 6.5 mm (L)

Temporary Abutment			
Product Name	s-Clean Temporary Abutment (Narrow)	MU Temporary Cylinder	s-Clean Temporary Abutment
Materials	Titanium Grade 4 / Non coating	Titanium Grade 4 / Non coating	Titanium Grade 4 / Non coating
Dimension	Ø 4.0 mm (D) x 12.5, 13 mm (L)	Ø 4.8 mm (D) x 10 mm (L)	Ø 4.8, 6.0 mm (D) x 13.8 mm (L)
O-ring Abutment			
Product Name	s-Clean O-Ring Abutment (Narrow)	-	s-Clean O-Ring Abutment
Materials	Ti-6Al-4V ELI / Non coating	-	Ti-6Al-4V ELI / Non coating
Dimension	Ø 3.5 mm (D) x 10, 12 mm (L)	-	Ø 3.4, 4.5 mm (D) x 10.1, 11.6, 13.6 mm (L)
Gold UCLA Abutment			
Product Name	s-Clean Gold UCLA Abutment (Narrow)	MU Gold Cylinder	s-Clean GOLD UCLA Abutment
Materials	Gold/Acetal Non coating	Gold/Acetal Non coating	Gold/Acetal Non coating
Dimension	Ø 4.0 mm (D) x 14.5, 15 mm (L)	Ø 4.8 mm (D) x 14.25 mm (L)	Ø 4.5 mm (D) x 14.4, 15.3 mm (L)
CCM Abutment			
Product Name	s-Clean CCM Abutment (Narrow)	MU CCM Cylinder	-
Materials	Co-Cr-Mo Alloy / Non coating	Co-Cr-Mo Alloy /Non coating	-
Dimension	Ø 4.0 mm (D) x 14.5, 15 mm (L)	Ø 4.8 mm (D) x 14.25 mm (L)	-
Abutment Screw			
Product Name	s-Clean Abutment Screw	MU Abutment Screw(2)	s-Clean Abutment Screw
Materials	Ti-6Al-4V ELI / Non coating	Ti-6Al-4V ELI / Non coating	Ti-6Al-4V ELI / Non coating
Dimension	Ø 2.03 mm (D) x 9 mm (L)	Ø 2.32 mm (D) x 7.8 mm (L)	Ø 2.3 mm (D) x 9.75, 9.95,10.5mm (L)

Healing Abutment		
K number	K161244 (Subject)	K073486
Product Name	s-Clean Healing Abutment (Narrow)	Healing Abutment
Intended Use	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 an endosseous dental implant that is indicated to use 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, and not indicated for single, unsplinted implants.
Materials	Titanium Grade 4 Non coating	Titanium Grade 4 Non coating
Dimension	Ø 4.0 mm (D) x 7.9, 8.4, 8.9, 9.4, 9.9, 10.4, 10.9, 11.4 mm (L)	Ø 4.5, 5.0, 5.5, 6.0 mm (D) x 1.0, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5 mm (Cuff L) Ø 6.5, 7.0 mm (D) x 1.5, 2.0, 2.5, 3.5, 4.5, 5.5 mm (Cuff L)

Substantial Equivalence Discussion

The subject device shares identical Indications for Use statement as the primary predicate device (K093321). The technological features of the subject device differ from the primary predicate in the following ways:

- Addition of 3.3 mm diameter implants
- Different abutment designs
- Different modified surfaces

The reference predicate, Paltop Narrow Implant (K130462), supports substantial equivalence of the subject device's 3.3 mm diameter implants. The reference predicates, Dentis Dental Implant System (K150344) and Dentis HAPTITE Implant System (K111364), contain identical types of abutment designs as the subject device, thus supporting the substantial equivalence of the subject device's abutments.

Non-Clinical Test Data

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

- Biocompatibility tests according to ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10 and ISO 10993-11.
- Fatigue Test according to ISO 14801:2007
- Endotoxin Test according to USP <85>

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
- End User Steam Sterilization Test according to ISO 17665-1,-2 and ANSI/AAMI ST79 referenced in K111364
- Shelf life Validation Test according to ISO 11607-1, -2, and ASTM F1980-07 referenced in K153639 and K073486

Modified surfaces characterization by Scanning Electron Microscopy and Energy Dispersive Spectroscopy have been performed to evaluate the substantial equivalence in the surface characteristics compared to the predicate devices according to "Guidance for Industry and Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments". The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device.
Fatigue evaluation was performed for demonstrating substantial equivalence under worst case scenario in accordance with ISO 14801 and "Guidance for Industry and Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".
The gamma sterilization validation, end user steam sterilization and shelf life validation testing were reference in the predicate devices.
Sterilization validation tests were performed for predicate device and leveraged for the subject device because the predicate device has bigger surface area and mass than the subject device, which is the worst case. The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Summary of clinical testing

No additional 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 OneQ-SL Narrow Implant System is substantially equivalent to the predicate devices as described herein.