DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 6, 2017

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

Re: K171027
Trade/Device Name: Dentis Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 31, 2017
Received: August 8, 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 (DICE) 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 (DICE) 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,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171027

Device Name
Dentis Dental Implant System

Indications for Use *(Describe)*
The Dentis Dental Implant System is an endosseous dental implant that 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 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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Dentis Co., Ltd.
99, Seongseoseo-ro, Dalseo-gu, Daegu, Korea
Tel : 82.53.582.2804 / Fax : 82.53.583.2806

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: Dentis Dental Implant System
Common Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 872.3640
Device Class: Class II
Date Prepared: 9/5/2017

Description
The Dentis Dental Implant System consists of three system, i-Clean System, s-Clean System, and e-Clean System. The purpose of this submission is to add various fixtures and abutment to the previously cleared device, K073486. Also, various set packing codes have been changed and it applies to the subject submission. Each system in the submission includes:

1) i-Clean System

Fixture
i-Clean Tapered Fixture/ i-Clean Straight Fixture / i-Clean Tapered II Fixture / i-Clean SAVE Fixture / i-Clean SAVE II Fixture
Abutment
i-Clean Cover Screw, i-Clean Closing Screw, i-Clean Solid Abutment, i-Clean Excellent Solid Abutment, i-Clean Healing Abutment, i-Clean Octa Abutment, i-Clean SynOcta Abutment, i-Clean InOcta Abutment, i-Clean Free Abutment, i-Clean Octa Healing Cap, i-Clean Gold UCLA, i-Clean Temporary Abutment, i-Clean Solid Healing Cap, i-Clean O-ring Abutment

2) s-Clean System

Fixture
s-Clean Tapered Fixture/ s-Clean Straight Fixture / s-Clean SAVE Fixture / s-Clean SAVE II Fixture

Abutment
s-Clean Cover Screw, s-Clean Healing Abutment, s-Clean Free Healing Abutment, s-Clean Couple Abutment, s-Clean Free Abutment, s-Clean Sole Abutment, s-Clean Sub-Octa Abutment, s-Clean Gold UCLA Abutment, s-Clean Temporary Abutment, s-Clean Sole Healing cap, s-Clean O-Ring Abutment, s-Clean Abutment screw, s-Clean CCM UCLA Abutment

3) e-Clean System

Fixture
e-Clean Tapered Fixture/ e-Clean Tapered II Fixture

Abutment
e-Clean Cover Screw, e-Clean Abutment Screw, e-Clean Mount Screw, e-Clean Healing Abutment ,e-Clean Cemented Abutment, e-Clean Gold UCLA Abutment, e-Clean Temporary Abutment(Ti), e-Clean O-Ring Abutment

The surface of the fixture has been treated with RBM (Resorbable Blasted media).

The dimensions of the fixtures are below:

<i-Clean Fixtures>

- i-Clean Tapered Fixture

Diameter	Length
Ø 3.7 mm	8, 10, 12, 14 mm
Ø 4.1mm	8, 10, 12, 14 mm
Ø 4.3mm	8, 10, 12, 14 mm
Ø 4.7mm	8, 10, 12, 14 mm

- i-Clean Straight Fixture

Diameter	Length
Ø 4.05 mm	8, 10, 12, 14mm
Ø 4.25mm	8, 10, 12, 14mm
Ø 4.75mm	8, 10, 12, 14mm

- i-Clean Tapered II Fixture

Diameter	Length
Ø 3.7 mm	8, 10, 12, 14 mm
Ø 4.1mm	8, 10, 12, 14 mm
Ø 4.3mm	8, 10, 12, 14 mm
Ø 4.7mm	8, 10, 12, 14 mm

- i-Clean SAVE Fixture

Diameter	Length
Ø 5.5mm	7, 8, 9, 10, 12 mm
Ø 6.0mm	7, 8, 9, 10, 12 mm

- i-Clean SAVE II Fixture

Diameter	Length
Ø 5.5mm	7, 8, 10, 12 mm
Ø 6.0mm	7, 8, 10, 12 mm

<s-Clean Fixtures>

- s-Clean Tapered Fixture

Diameter	Length
Ø 3.7 mm	8, 10, 12, 14 mm
Ø 4.1mm	8, 10, 12, 14 mm
Ø 4.3mm	8, 10, 12, 14 mm
Ø 4.8mm	8, 10, 12, 14 mm

- s-Clean Straight Fixture

Diameter	Length
Ø 4.1mm	8, 10, 12, 14, 16 mm
Ø 4.3mm	8, 10, 12, 14, 16 mm
Ø 4.75mm	8, 10, 12, 14, 16 mm

- s-Clean SAVE Fixture

Diameter	Length
Ø 5.5mm	7, 8, 9, 10, 12 mm
Ø 6.0mm	7, 8, 9, 10, 12 mm

- s-Clean SAVE II Fixture

Diameter	Length
Ø 5.5mm	7, 8, 9, 10, 12 mm
Ø 6.0mm	7, 8, 9, 10, 12 mm

<e-Clean Fixtures>

- e-Clean Tapered Fixture

Diameter	Length
Ø 3.5mm	8, 10, 12, 14 mm
Ø 4.1mm	8, 10, 12, 14 mm
Ø 5.1mm	8, 10, 12, 14 mm

- e-Clean Tapered II Fixture

Diameter	Length
Ø3.5mm	8, 10, 12, 14 mm
Ø4.1mm	8, 10, 12, 14 mm
Ø5.1mm	8, 10, 12, 14 mm

The packaging has composed of fixture with cover screw. The fixtures, cover screws and healing abutments are supplied sterile by gamma sterilization. The fixtures are provided as set-packing with the cover screws. The abutments are provided separately and should be sterilized by user before use.

Indication for Use

The Dentis Dental Implant System is an endosseous dental implant that 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 when good primary stability has been achieved and with appropriate occlusal loading.

Predicate Devices & Comparison

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

- K073486, Dentis Dental Implant System by Dentis Co., Ltd. - Primary predicate
- K142313, OneQ-SL s-Clean Implant System by Dentis Co., Ltd.
- K161244, s-Clean OneQ-SL Narrow System by Dentis Co., Ltd.

① Fixtures

a. i-Clean System

	Subject device	Primary Predicate device	Reference Predicate Device	Reference Predicate Device
Device name	Dentis Dental Implant System	Dentis Dental Implant System	OneQ-SL s-Clean Implant System	s-Clean OneQ-SL Narrow Implant System
510(k) number	NA	K073486	K142313	K161244
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.
Intended use	The Dentis Dental Implant System is an endosseous dental implant that 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	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	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 dedicated	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

	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 when good primary stability has been achieved and with appropriate occlusal loading.	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.	for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.	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.
Material	CP Titanium Gr.4	CP Titanium Gr.4	CP Titanium Gr.4	Ti-6Al-4V ELI
Design	Tapered, Straight, Tapered II, SAVE, and SAVE II designs, each with 8° internal connect octa	• Tapered: Internal Hex connected • SAVE: Abutment with connection of 8° morse taper shape	• Internal Hex-connected • Bone level • Tapered & straight body	• Straight and tapered implant body • 3 sided cutting edge of bottom • Internal double hex connection • Bone level design.
Platform Diameter(Coronal)	4.8~6.0mm	4.8~6.5mm	4.8~6.5mm	-
Fixture diameter (Ø)	3.7, 4.1, 4.3, 4.7, 5.5, 6.0, mm	3.5, 3.7, 4.1, 4.3, 4.8, 5.5, 6.0mm	3.7, 3.9, 4.2, 4.7, 5.2, 6.0, 7.0 mm	3.0, 3.3 mm
Fixture length	7, 8, 9, 10, 12, 14 mm	7, 8, 10, 12, 14 mm	7, 8, 10 ,12, 14 mm	10 ,12, 14 mm
Surface treatment	RBM	RBM	SLA	SLA

Gamma sterilized	Yes	Yes	Yes	Yes
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Shelf Life	8 years	2 years	1 years	8 years
Brief Comparison	- Similarities: The subject device has equivalent indications for use, material, surface treatment, dimension, sterilization, and shelf life as predicate devices. - Differences: New fixtures added to include Straight, Tapered II, and SAVE II designs that have slightly different thread profiles and sizes; new diameter sizes added for Tapered (Ø 4.1, 4.7mm) and SAVE (Ø 5.5, 6.0mm) designs. All fixtures with new co-packaging to include Cover Screw. With different shapes and sizes added, leveraged information from fixtures in predicate (K073486) justified to show worst case by comparing the measurements of proposed fixtures from each system. Therefore, addition of fixtures does not raise any risks and questions. The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244), supports substantial equivalence of shelf life.			

b. s-Clean System

	Subject device	Predicate device	Reference Predicate Device	Reference Predicate Device
Device name	Dentis Dental Implant System	Dentis Dental Implant System	OneQ-SL s-Clean Implant System	s-Clean OneQ-SL Narrow Implant System
510(k) number	NA	K073486	K153639	K161244
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.
Intended use	The Dentis Dental Implant System is an endosseous dental implant that 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	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	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

	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 when good primary stability has been achieved and with appropriate occlusal loading.	loading. Immediate loading is restricted to the anterior mandible based on four splinted Interforaminal placed implants.		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.
Material	CP Titanium Gr.4	CP Titanium Gr.4	CP Titanium Gr.4	Ti-6Al-4V ELI
Design	Tapered, SAVE, Straight, and SAVE II designs, each Internal Hex connected	- Tapered: Internal Hex connected, Submerged, micro-thread design - SAVE: Abutment with connection of 11° morse taper shape, micro-thread design	• Internal Hex-connected • Bone level • Tapered & straight body	• Straight and tapered implant body • 3 sided cutting edge of bottom • Internal double hex connection • Bone level design.
Fixture diameter (Ø)	3.7, 4.1, 4.3, 4.8, 5.5, 6.0mm	3.5, 3.7, 4.1, 4.3, 4.8, 5.5, 6.0mm	3.7, 3.9, 4.2, 4.7, 5.2, 6.0, 7.0, 7.0 mm	3.0, 3.3 mm
Fixture length	7, 8, 9, 10, 12, 14 mm	7, 8, 10, 12, 14 mm	7, 8, 10 ,12, 14 mm	10 ,12, 14 mm
Surface treatment	RBM	RBM	SLA	SLA
Gamma sterilized	Yes	Yes	Yes	Yes
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Shelf Life	8 years	2 years	1 years	8 years

Brief Comparison	- Similarities: The subject device has equivalent indications for use, material, surface treatment, dimension, sterilization, and shelf life as predicate devices. - Differences: New fixtures added to include Straight and SAVE II designs that have slightly different thread profiles and sizes; new diameter sizes added for Tapered (Ø 4.1mm) and SAVE (Ø 5.5mm) designs. All fixtures with new co-packaging to include Cover Screw. With different shapes and sizes added, leveraged information from fixtures in predicate (K073486) justified to show worst case by comparing the measurements of proposed fixtures from each system. Therefore, addition of fixtures does not raise any risks and questions. The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244), supports substantial equivalence of shelf life.

c. e-Clean System

	Subject device	Predicate device	Reference Predicate Device	Reference Predicate Device
Device name	Dentis Dental Implant System	Dentis Dental Implant System	OneQ-SL s-Clean Implant System	s-Clean OneQ-SL Narrow Implant System
510(k) number	NA	K073486	K153639	K161244
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.
Intended use	The Dentis Dental Implant System is an endosseous dental implant that 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 when good primary stability has been	DENTIS implant is designed for use in edentulous sites in the mandible or maxilla for support for a complete denture prosthesis, terminal or intermediate abutment for fixed bridgework, partial dentures, or single tooth replacements.	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.

	achieved and with appropriate occlusal loading.			The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.
Material	CP Titanium Gr.4	Commercially pure titanium GR.4 (ASTM-F-67)	CP Titanium Gr.4	Ti-6Al-4V ELI
Design	Tapered and Tapered II designs, each External Hex connected	Internal Hex connected, Submerged, External Hex connected	• Internal Hex-connected • Bone level • Tapered & straight body	• Straight and tapered implant body • 3 sided cutting edge of bottom • Internal double hex connection • Bone level design.
Fixture diameter (Ø)	3.5, 4.1, 5.1mm	3.3, 3.5, 4.1, 5.1mm	3.7, 3.9, 4.2, 4.7, 5.2 mm	3.0, 3.3 mm
Fixture length	8, 10, 12, 14 mm	8, 10, 12, 14 mm	7, 8, 10 ,12, 14 mm	10 ,12, 14 mm
Surface treatment	RBM	RBM	SLA	SLA
Gamma sterilized	Yes	Yes	Yes	Yes
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Shelf Life	8 years	2 years	1years	8 years
Brief Comparison	- Similarities: The subject device has equivalent indications for use, material, surface treatment, dimension, sterilization, and shelf life as predicate devices. - Differences: New fixture added to include Tapered II design that has slightly different tread profiles and sizes. All fixtures with new co-packaging to include Cover Screw or Cover Screw with Mount and Mount Screw. With different shapes and sizes added, leveraged information from fixtures in predicate (K073486) justified to show worst case by comparing the measurements of proposed fixtures from each system. Therefore, addition of fixtures does not raise any risks and questions. The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244), supports substantial equivalence of shelf life.			

② **Abutment**

a. i-Clean System

	Subject device	Primary Predicate	Reference Predicate
510(k) number	NA	K073486	K161244
Product Name	Solid Abutment	Solid Abutment	-
Dimension	Ø3.5 mm (D) x 8, 9, 10.5, 12mm (L)	Ø3.5 mm (D) x 9, 10.5, 12 mm (Length)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Product Name	Excellent Solid Abutment	Excellent Solid Abutment	-
Dimension	Ø4.3 mm (D) x 7.88, 8.78, 10.38, 11.88mm (L)	Ø4.3 mm (D) x 8.78, 10.38, 11.88mm (L)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Product Name	Octa Abutment	Octa Abutment	-
Dimension	Ø3.5, 4.3mm (D) x 7, 7.3mm (L)	Ø3.5mm (D) x 7mm (L)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Product Name	SynOcta Abutment	SynOcta Abutment	-
Dimension	Ø3.5mm (D) x 8.3 mm (L)	Ø3.5mm (D) x 8.3 mm (L)	-
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	-
Product Name	Healing Abutment	Healing Abutment	Healing Abutment
Dimension	Ø5.5, 6.4, 6.9mm(D) x 7.1, 8.1, 8.3, 9.1, 9.3 9.6, 10.6, 10.8 12.1mm(L)	Ø5.5, 6.4, 6.9mm(D) x 8.1, 9.1, 10.6mm(L)	Ø4.0 mm(D) x 7.9, 8.4, 8.9, 9.4, 9.9, 10.4,10.9,11.4mm(L)
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)
Product Name	InOcta Abutment	InOcta Abutment	-
Dimension	Ø5.2, 6.9 mm (D) x 8.75, 9.75, 10.75, 11.75, 8.85, 9.85, 10.85, 11.85 mm (L)	Ø5.2mm (D) x 8.75, 9.75, 10.75, 11.75mm (L)	-
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	-
Product Name	Temporary Abutment	Temporary Abutment	Temporary Abutment

Dimension	Ø5.0, 5.2, 6.8 6.9 mm (D) x 11.5 12.75, 13.75, 14.75, 15.75, 12.85, 13.85, 14.85, 15.85 mm (L)	Ø5.0 5.2 mm (-D) x 11.5 12.75, 13.75, -14.75,mm (L)	Ø 4.0 mm (D) x 12.5 and 13 mm (L)
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)
Product Name	Octa Healing Cap	Octa Healing Cap	-
Dimension	Ø4.9, 6.6mm (D) x 4.0, 4.3 mm (L)	Ø4.9mm (D) x 4.0 mm (L)	-
Material	Acetal, Pure Titanium (Grade 4)	Acetal, Pure Titanium (Grade 4)	-
Product Name	Gold UCLA Abutment	Gold UCLA Abutment	Gold UCLA Abutment
Dimension	Ø5.0, 5.1, 6.8 mm (D) x 14.25, 14.3, 14.65, 14.7, 15.6mm (L)	Ø5.0, 5.1mm (D) x 14.3,14.7mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Material	Gold Alloy, Acetal	Gold Alloy, Acetal	Gold Alloy, Acetal
Product Name	Solid Healing Cap	Solid Healing Cap	Healing Cap
Dimension	Ø5.4, 5.5, 5.9, 7mm (D) x 4.7, 5.5, 6.4, 6.5, 8.0, 9.4, 9.5mm (L)	Ø5.5, 5.9 mm (D) x 4, 5.5, 7mm (L)	Ø 4.6 mm (D) x 6, 7.5 and 9 mm (L)
Material	Acetal	Acetal	Acetal
Product Name	O-ring Abutment	O-ring Abutment	O-ring Abutment
Dimension	Ø3.5, 4.3mm (D) x 9.1, 9.4, 11.1, 11.4, 13.1, 13.4 mm (L)	Ø3.5mm (D) x 9.1,11.1,13.1mm (L)	Ø 3.5 mm (D) x 10 and 12 mm (L)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)
Sterilization	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user
Product Code	NHA	NHA	NHA
Shelf Life of Healing Abutment	8 years	5 years	8 years
Sterilization method for Healing abutment	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Brief Comparison	The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244) supports substantial equivalence of shelf life of healing abutment.		

b. s-Clean System

	Subject device	Primary Predicate	Reference Predicate
510(k) number	NA	K073486	K161244
Product Name	Healing Abutment	Healing Abutment	Healing Abutment
Dimension	Ø 4.0, 4.5, 4.8, 5.0, 5.5, 6.0,6.5,7.0, 7.5mm (D) X 9.5, 10.0, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5, 14.0 mm (L)	Ø 4.5, 5.0, 5.5, 6.0, 6.5,7.0mm (D) X 9.5, 10.0, 10.5, 11.0, 12.0, 13.0, 13.5, 14.0 mm (L)	Ø4.0 mm(D) x 7.9, 8.4, 8.9, 9.4, 9.9, 10.4,10.9,11.4mm(L)
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)
Product Name	Free Healing Abutment	Free Healing Abutment	-
Dimension	Ø 4.0, 4.5, 5.5, 6.5mm(D) x 8.8, 9.3, 10.8, 11.3mm(L)	Ø 4.5, 5.5mm(D) x 9.3,11.3mm(L)	-
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	-
Product Name	Sole Abutment Healing Cap	Sole Abutment Healing Cap	-
Dimension	Ø5.1, 5.8, 6.3, 6.8mm (D) x 7 mm (L)	Ø4.5, 5.5, 6.5mm(D) x 7mm(L)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Product Name	Sole Abutment	Sole Abutment	Sole Abutment
Dimension	Ø4.5, 4.8, 5.5, 6.0, 6.5 mm (D) x 12.5, 13.0, 13.5, 14,15, 16, 17 mm (L)	Ø4.5, 5.5, 6.5 x 0.8, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5mm(Cuff)	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)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)
Product Name	Couple Abutment	Couple Abutment	-
Dimension	Ø4.0, 4.5, 4.8, 5.5, 6.0, 6.5 mm (D) x 7.3, 7.44, 7.8, 7.94, 8.3, 8.44, 8.94, 8.8, 8.94, 9.3, 9.44, 9.8, 9.94, 10.3, 10.94, 10.44, 10.8, 10.94, 11.3,11.44, 11.8, 11.94, 12.3, 12.44,12.8, 12.94, 13.8, 13.3, 13.44, 13.94, 14.8, 14.94 mm (L)	Ø4.5,5.5, 6.5mm (D) x 1.0, 1.5, 2.0,2.5, 3.5, 4.5, 5.5 mm (Cuff)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Product Name	O-Ring Abutment	O-Ring Abutment	O-Ring Abutment

Dimension	Ø3.4, 4.5mm (D) x 10.1, 11.6, 13.6 mm (L)	Ø3.4, 4.5mm(D) x 0.5, 2, 4mm(Cuff)	Ø 3.5 mm (D) x 10, 12 mm (L)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI (Grade 5)
Product Name	Sub-Octa Abutment	Sub-Octa Abutment	-
Dimension	Ø4.8mm (D) x 9.15, 9.65, 10.65, 11.65, 12.65, 13.65 mm (L)	Ø4.8mm(D) x 1.0, 1.5, 2.5, 3.5, 4.5, 5.5mm (Cuff)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Product Name	Abutment screw	Abutment screw	Abutment screw
Dimension	Ø2.32mm (D) x 8.8, 9.2, 9.4, 9.8, 9.95, 10.5 mm (L)	Ø2.32mm(D) x 9.8mm(L)	Ø 2.03 mm (D) x 9 mm (L)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)
Product Name	Temporary Abutment	Temporary Abutment	Temporary Abutment
Dimension	Ø4.5, 4.8, 5.5, 6.0, 6.5mm (D) x 13.54, 13.4 mm (L)	Ø4.5, 5.5, 6.5mm(D) x 13.54, 13.4mm (L)	Ø 4.0 mm (D) x 12.5 and 13 mm (L)
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)
Product Name	Gold UCLA Abutment	Gold UCLA Abutment	Gold UCLA Abutment
Dimension	Ø4.5 mm (D) x 15.34, 15.4 mm (L)	Ø4.5 mm (D) x 15.34, 15.4 mm (L)	Ø 4.0 mm (D) x 14.5, 15 mm (L)
Material	Gold Alloy, Acetal	Gold Alloy, Acetal	Gold Alloy, Acetal
Product Name	CCM Abutment	-	CCM Abutment
Dimension	Ø4.5 mm (D) x 15.39, 15.44 mm (L)	-	Ø 4.0 mm (D) x 14.5, 15 mm (L)
Material	Co-Cr-Mo Alloy	-	Co-Cr-Mo Alloy
Sterilization	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user
Product Code	NHA	NHA	NHA
Shelf Life of Healing Abutment	8 years	5 years	8 years
Sterilization method for Healing abutment	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Brief Comparison	The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244) supports substantial equivalence of shelf life.		

- s-Clean Temporary abutment made of PEEK material

	Subject Device	Previously Cleared Product
510(K) Number	K171027	K150344
Manufacturer	Dentis Co., Ltd	Dentis Co., Ltd.
Device Name	Dentis Dental Implant System	Dentis Dental Implant System
Model Name	Temporary Abutment	MU Click Bridge Cap
Manufacturing Process	Identical	Identical
Materials	Identical	PEEK (Polyether ether ketone)
Body contact	Identical	Direct (Mucosal Membrane)
Contact Duration	Identical	Class B (> 24hr, <30 days)
Brief Comparison	The Peek material used for the subject device and predicate device (K150344) is exactly same from same manufacturer. We provided the full biocompatibility test report of the Peek material in K150344. The test reports support substantial equivalences because same manufacturing process and material are used for subject and predicate devices.	

c. e-Clean System

	Subject device	Primary Predicate	Reference Predicate
510(k) number	NA	K073486	K161244
Product Name	Healing Abutment	Healing Abutment	Healing Abutment
Dimension	Ø4.0, 5.0, 6.0, mm (D) x 7.4, 8.4, 9.4, 10.9, 12.4 mm (L)	Ø4.0, 5.0, 6.0mm(D) x 2.0, ..0, 4.0, 5.5, 7.0mm (Cuff)	Ø4.0 mm(D) x 7.9, 8.4, 8.9, 9.4, 9.9, 10.4,10.9,11.4mm(L)
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)
Product Name	Cemented Abutment	Cemented Abutment	-
Dimension	Ø4, 5, 6 mm (D) x 7, 8, 9, 10, 11, 12 mm (L)	Ø4, 5, 6mm(D) x 6, 8mm(L)	-
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	-
Product Name	Gold UCLA Abutment	Gold UCLA Abutment	Gold UCLA Abutment
Dimension	Ø4, 4.5, 5.5, mm (D) x 13.2 mm (L)	Ø4, 4.5, 5.5, mm (D) x 13.2 mm (L)	Ø 4.0 mm (D) x 14.5 and 15 mm (L)
Material	Gold Alloy, Acetal	Gold Alloy, Acetal	Gold Alloy, Acetal
Product Name	Temporary Abutment	Temporary Abutment	Temporary Abutment
Dimension	Ø4, 4.5, 5.5, mm (D) x 12 mm (L)	Ø4, 4.5, 5.5, mm (D) x 12 mm (L)	Ø 4.0 mm (D) x 12.5 and 13 mm (L)

Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)
Product Name	O-ring Abutment	O-ring Abutment	O-ring Abutment
Dimension	Ø5,6mm (D) x 10.2, 12.2 mm (L)	Ø5,6mm (D) x 10.2, 12.2 mm (L)	Ø 3.5 mm (D) x 10 and 12 mm (L)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)
Sterilization	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user
Product Code	NHA	NHA	NHA
Shelf Life of Healing Abutment	8 years	5 years	8 years
Sterilization method for Healing abutment	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Brief Comparison	The reference predicates, s-Clean OneQ-SL Narrow Implant System (K161244) supports substantial equivalence of shelf life.		

Substantial Equivalence Discussion

The Dentis Dental Implant System has a substantially equivalent intended use as the identified predicate. The subject device is identical 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 identical in indication for use, material, connection structure, packaging, function, using abutments, performance, design, technology and dimensions. The subject device is the modification to the predicate, K073486 by adding various sizes of fixtures and abutments and new set codes.

Non-Clinical Test Data

The following test was performed for this subject system:

- Limulus amebocyte lysate (LAL) test plan for endotoxin sampling of devices labeled as sterile, in accordance with USP <85> and USP <161>

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

- Biocompatibility Tests for PEEK material based on ISO 10993-5:2009 (Cytotoxicity), ISO 10993-10:2010 (Sensitization and Irritation) referenced in K150344
- Sterilization Test according to ISO 11137-1,-2,-3 referenced in K073486
- End user sterilization test according to ISO 17665-1, -2 referenced in K161244
- Shelf life Validation Test according to ISO 11607-1, -2, and ASTM F1980-07 referenced in K153639 (Fixtures) and K161244 (Fixtures and Healing Abutment)

The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device.

The fixture materials of the pure titanium and Ti-6Al-4V ELI are biocompatible because both materials were cleared in K073486 and it demonstrates substantial equivalence of materials.

The Peek material used for the subject device and predicate device (K150344) is exactly same from same manufacturer. We provided the full biocompatibility test report of the Peek material in K150344. The test

reports support substantial equivalences because same manufacturing process and material are used for subject and predicate devices.
The sterilization validation test was performed for predicate device, K073486 and leveraged for the subject device because the sterilization method, standard, facility, and SAL are exactly same.
The RBM surface characterization was provided in the predicate device, K073486 according to "Guidance for FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant Abutments and it is exactly same for the subject device.
The reference predicates, OneQ SL s-Clean Implant System (K153639) and s-Clean OneQ-SL Narrow Implant System (K161244), supports substantial equivalence of shelf life.

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 Dentis Dental Implant System is substantially equivalent to the predicate devices as described herein