November 29, 2017

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

Re: K171694
Trade/Device Name: s-Clean TiN Coating Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 25, 2017
Received: October 31, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171694

Device Name
s-Clean TiN Coating Abutments

Indications for Use *(Describe)*
The s-Clean TiN Coating Abutments 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

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Device Information
Trade Name: s-Clean TiN Coating Abutments
Common Name: Dental Abutment
Classification Name: Endosseous Dental Abutment
Product Code: NHA
Panel: Dental
Regulation Number: 872.3630
Device Class: Class II
Date Prepared: 11/20/2017

Description
The s-Clean TiN Coating Abutments are device made of pure titanium and titanium alloy intended for use as an aid in prosthetic restoration.

The system consists of s-Clean TiN Half Coating Angled Abutment, s-Clean TiN Half and partial Coating Couple Abutment, s-Clean TiN Half Coating Free Abutment, s-Clean TiN Half Coating FreeMill Abutment, s-Clean TiN Half Coating MOA Abutment, s-Clean TiN Partial Sub-Octa Abutment, s-Clean TiN Partial Coating Sole Abutment, s-Clean DOA Ball Abutment, s-Clean DOA Snap Abutment, and s-Clean Sole Abutment Healing Cap.

The dimension of each abutment ranges as below:

- s-Clean TiN Half Coating Angled Abutment: Ø4.5, 5.0, 5.5 and 6.5 mm (D) x 10.18, 10.6, 10.46, 11.04, 11.18, 11.46, 11.6, 13.04, 13.18, 13.46 and 13.6 mm (L) x 15° and 25°
- s-Clean TiN Half and Partial Coating Couple Abutment: Ø4.5, 4.8, 5.5 and 6.5 mm (D) x 0.8, 1.3, 1.8, 2.3, 3.3, 4.3 and 5.3mm (Cuff H)
- s-Clean TiN Half Coating Free Abutment: Ø4.5, 5.5 and 6.5mm (D) x 15.36 and 15.5mm (L)
- s-Clean TiN Half Coating FreeMill Abutment: Ø4.0, 4.5, 5.5, 6.5mm (D) and 7.5mm (D) x 1.3, 1.8, 2.8, 3.8 mm (Cuff H)
- s-Clean TiN Half Coating MOA Abutment: Ø4.5 and 5.5mm(D) x 12.64, 14.14, 14.64, 15.14 and 16.14mm(L)
- s-Clean TiN Partial Sub-Octa Abutment: Ø 4.8 mm (D) x 0.8, 1.3, 2.3, 3.3, 4.3 and 5.3 mm (Cuff H)
- s-Clean TiN Partial Coating Sole Abutment: Ø4.5, 5.5, 6.0 and 6.5 mm (D) x 0.8, 1.3, 1.8, 2.3, 4.3, and 5.3mm (Cuff H)

- s-Clean DOA Ball Abutment: Ø3.5 mm (D) x 0.6, 1.6, 2.6, 4.6, 5.6 (Cuff H)
- s-Clean DOA Snap Abutment: Ø3.5 mm (D) x 3.35 (Cuff H)
- s-Clean Sole Abutment Healing Cap: Ø4.6, 5.1, 5.9, 6.3, 6.8 and 6.9mm (D) x 6, 7, 7.5 and 9 mm (L)

The surface of the abutments is partially or half TiN Coated by using PVD (Physical Vapor Deposition).

The subject device is compatible with:

Compatible Implant names	Implant Models	Sizes
Dentis Dental Implant System (K171027)	s-Clean Tapered Fixture s-Clean SAVE Fixture	Diameters: Ø3.7, 4.3, 4.8, 5.5, 6.0
		Length: 7, 8, 10, 12, 14mm
Dentis Dental Implant System (K082843)	s-Clean SAVE Fixture	Diameters: Ø6.5, 7.0
		Lengths:7, 8, 10, 12mm
Haptite Coating Implant System (K111364)	HAPTITE s-Clean Tapered Fixture HAPTITE s-Clean Straight Fixture HAPTITE s-Clean SAVE Fixture	Diameters: Ø3.7, 4.1, 4.3, 4.8, 5.5, 6.0, 6.5, 7.0
		Lengths:7, 8, 10, 12, 14mm
Dentis Dental Implant System (K150344)	s-Clean Tapered Fixture	Diameters: Ø3.7, 4.1, 4.8
		Lengths:7, 8, 10, 12, 14mm
oneq-sl s-clean implant system (K153639)	OneQ-SL s-Clean Fixture	Diameters: Ø 3.7, 3.9, 4.2, 5.2, 6.0, 7.0, 8.0
		Lengths:7, 8, 10, 12, 14mm
s-clean tapered ii rbm implant system (K160213)	s-Clean Tapered II RBM Fixture	Diameters: Ø3.7, 4.1, 4.3, 4.8
		Lengths:7, 8, 9, 10, 12, 14mm

The subject device is provided non-sterile and should be sterilized before use (End user sterilization).

Indication for Use

The s-Clean TiN Coating Abutments 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 Device & Comparison

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

Primary Predicate

- K171027, Dentis Dental Implant System by Dentis Co., Ltd.

Reference Predicates

- K082843, Dentis Dental Implant System by Dentis Co., Ltd.
- K111364, Haptite Coating Implant System by Dentis Co., Ltd.
- K161244, S-Clean Oneq-sl Narrow Implant System by Dentis Co., Ltd.
- K153521, IH Prosthetic System by Sewon Medix Inc.
- K142211, OT Equator by Rhein'83 Srl.

	Subject device	Primary Predicate	Reference Predicate	Reference Predicate	Reference Predicate
510(k) number	NA	K171027	K082843	K111364	K153521
Product Name	s-Clean TiN Coating Abutments	Dentis Dental Implant System	Dentis Dental Implant System	Haptite Coating Implant System	IH Prosthetic System
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.	Dentis Co., Ltd.	Sewonmedix Inc.
Indications for Use	The s-Clean TiN Coating Abutments 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	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	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	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	IH Implant System is device made of titanium and titanium alloy indicated for in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained or screw retained restorations and terminal or interminal abutment support for fixed

	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.	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.	two stage surgical procedures and not for immediate load. Also, this system is intended to be used in the molar region.	is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.	bridgework. IH Implant System is for single and two stage surgical procedures. It is intended for delayed loading.
Product Name	s-Clean TiN Half Coating Angled Abutment	-	Submerged Angled Abutment	-	Angled Abutment
Dimension	Ø4.5, 5.0, 5.5 and 6.5 mm (D) x 10.18, 10.6, 10.46, 11.04, 11.18, 11.46, 11.6, 13.04, 13.18, 13.46 and 13.6 mm (L) x 15° and 25°	-	Ø4.5, 5.0, 5.5 and 6.5 mm (D) x 9, 10.5, 12 mm (L)	-	Ø 4.5/5.0/5.5 /6.0 X 9..5,10,10.5, 11,11.5,12 (L)
Material	Ti-6Al-4V ELI(Grade 5)	-	Ti-6Al-4V ELI(Grade 5)	-	Ti-6Al-4V ELI(Grade 5)
Coating	TiN coating	-	NA	-	TiN coating
Angulation	15°/25°	-	15°/25°	-	15°/25°
Product Name	s-Clean TiN Half Coating Couple Abutment	Couple Abutment	-	-	Cement Abutment

Dimension	Ø4.5, 4.8, 5.5 and 6.5 mm (D) x 0.8, 1.3, 1.8, 2.3, 3.3, 4.3 and 5.3mm (Cuff H)	Ø4.0, 4.5, 4.8, 5.5, 6.0 and 6.5 mm (D) x 0.8, 1.3, 1.8, 2.3, 3.3, 4.3 and 5.3mm (Cuff H)	-	-	Ø4.5/5.0/5.5 /6.0 /6.5 X 1.0/1.5/2.0/ 2.5 /3.0/3.5/4.0/4.5/5.0 (Cuff H)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-	-	Ti-6Al-4V ELI(Grade 5)
Coating	TiN coating	NA	-	-	TiN coating
Product Name	s-Clean TiN Half Coating Free Abutment	Free Abutment	-	-	-
Dimension	Ø4.5, 5.5 and 6.5mm (D) x 15.36 and 15.5mm (L)	Ø4.5 and 5.5 and 6.5mm (D) x 15.36 and 15.5mm (L)	-	-	-
Material	Pure Titanium (Grade 4)	Pure Titanium (Grade 4)	-	-	-
Coating	TiN coating	NA		-	-
Product Name	s-Clean TiN Half Coating FreeMill Abutment	-	-	-	FreeMilling Abutment
Dimension	Ø4.0, 4.5, 5.5, 6.5mm (D) and 7.5mm (D) x 1.3, 1.8, 2.8, 3.8 mm (Cuff H)	-	-	-	Ø 4.5/5.0 /5.5/6.0/6.5mm (D) x 1.0/2.0 /3.0mm (Cuff H)
Material	Pure Titanium (Grade 4)	-	-	-	Pure Titanium (Grade 4)

Coating	TiN coating	-	-	-	TiN coating
Product Name	s-Clean TiN Half Coating MOA Abutment	-	-	MOA Abutment	-
Dimension	Ø4.5 and 5.5mm(D) x 12.64, 14.14, 14.64, 15.14 and 16.14mm(L)	-	-	Ø4.0 and 5.5mm(D) x 12.64, 14.14, 14.64, 15.14 and 16.14mm(L)	-
Material	Ti-6Al-4V ELI(Grade 5)	-	-	Ti-6Al-4V ELI(Grade 5)	-
Coating	TiN coating	-	-	-	-
Product Name	s-Clean TiN Partial Coating Sub-Octa Abutment	Sub-Octa Abutment	-	-	-
Dimension	Ø4.8 mm (D) x 0.8, 1.3, 2.3, 3.3, 4.3 and 5.3 mm (Cuff H)	Ø4.8mm (D) x 0.8, 1.3, 2.3, 3.3, 4.3 and 5.3 mm (Cuff H)	-	-	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-	-	-
Coating	TiN coating	-	-	-	-
Product Name	s-Clean TiN Partial Coating Sole Abutment	Sole Abutment	-	-	Solid Abutment
Dimension	Ø4.5, 5.5, 6.0 and 6.5 mm (D) x 0.8, 1.3, 1.8,	Ø4.5, 5.5, 6.0 and 6.5 mm (D) x 0.8, 1.3, 1.8,	-	-	Ø4.0/4.5/5.0/5.5/ 6.0/6.5/7.0 X 1.0/1.5/2.0/2.5/

	2.3, 4.3, and 5.3mm (Cuff H)	2.3 4.3 and 5.3mm (Cuff H)			3.0/3.5/4.0/4.5/5.0 (L)
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-	-	Ti-6Al-4V ELI(Grade 5)
Coating	TiN coating	-	-	-	TiN coating
Product Name	s-Clean DOA Ball Abutment	O-Ring Abutment	-	-	-
Dimension	Ø3.5 mm (D) x 1.0, 2.0, 3.0, 4.0, 5.0(Cuff H)	Ø3.5 mm (D) x 0.5, 2 and 4 mm (Cuff H)	-	-	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-	-	-
Coating	TiN coating	-	-	-	-
Product Name	Sole Healing Cap	-	-	Sole Healing Cap	-
Dimension	Ø4.6, 5.1, 5.9, 6.3, 6.8 and 6.9mm (D) x 6, 7, 7.5 and 9 mm (L)	-	-	Ø4.9mm (D) x 4.0 mm (L)	-
Material	Acetal	-	-	Acetal	-
Sterilization	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user	Steam sterilization by user	-
Product Code	NHA	NHA	NHA	NHA	-
Brief Discussion	The subject device is similar to the predicate devices in shape, angulation, structure, dimension, and material. The difference is TiN coated surface treatment of the abutments.				

s-Clean DOA Snap Abutment

	Subject device	Primary Predicate	Reference Predicate
510(k) number	NA	K142211	K171027
Product Name	s-Clean TiN Coating Abutments	OT EQUATOR	Dentis Dental Implant System
Manufacturer	Dentis Co., Ltd.	Rhein'83 Srl	Dentis Co., Ltd.
Indications for Use	The s-Clean TiN Coating Abutments 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.	The OT Equator is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The OT Equator is screwed into an endosseous implant in the mandible or maxilla. The OT Equator abutments are indicated for use with the implant systems listed in Attachment B.	The Dentis 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. Patients must be subject for dental treatment with endosseous implants.
Product Name	s-Clean DOA Snap Abutment	OT Equator Abutment	-
Dimension	Ø3.5 mm (D) x 3.35 (Cuff H)	Ø2.5 mm (D) x 1-7 mm(Cuff H)	-
Material	Ti-6Al-4V ELI(Grade 5)	Ti-6Al-4V ELI(Grade 5)	-
Coating	TiN coating	TiN coating	-

Non-Clinical Test Data

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

- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2006.
- Fatigue Testing according to ISO 14801:2007

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

- End User Steam Sterilization Test according to ISO 17665-1:2006, -2:2009 and ANSI/AAMI ST79 referenced in K161244

The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device.
Biocompatibility Test was conducted for the subject devices and it demonstrates that the subject device is biocompatible and substantial equivalence with the predicate device, K153521.
The end user sterilization test was performed for predicate device, K161244 and leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging is the exactly the same as the predicate, K161244.
Fatigue evaluation was performed on the subject device 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 non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Summary of clinical testing

No clinical testing was performed for this submission.

Substantial Equivalence Discussion

Similarities:

The subject device has identical material, machining, manufacturing process, angulation and indication for use and similar design, dimension and technological characteristics as the predicate devices.

The subject device has been supposed to performance and product validations prior to release. Testing including biocompatibility tests and fatigue test has been performed to ensure the devices comply with the applicable International and US FDA Guidance.

Differences:

The differences between the subject device and predicate devices are detailed shape and dimension of each abutment and area of TiN Coated surface treatment.

Any differences between the subject device and predicate devices do not raise new types of substantially equivalent issues.

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 TiN Coating Abutments is substantially equivalent to the predicate devices as described herein.