Dentis Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

August 19, 2021

Re: K210362
Trade/Device Name: s-Clean Pre-Milled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 13, 2021
Received: July 19, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210362

Device Name
s-Clean Pre-Milled Abutment

Indications for Use *(Describe)*
s-Clean Pre-Milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

No.	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
1	s-Clean SQ-SL Fixture	Ø5.8	Ø4.3
2		Ø6.8	Ø4.5

s-Clean Pre-Milled Abutment is intended for use with the s-Clean SQ-SL Fixtures in the chart. All digitally designed abutments for use with s-Clean Pre-Milled Abutment are intended to be manufactured at a Dentis validated milling center.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Fax: 1-909-460-8122

Device Information

- Trade Name: s-Clean Pre-Milled Abutment
- Common Name: Dental Abutment System
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 08/18/2021

Predicate Devices:

Primary Predicate

K181037, DIO CAD/CAM Abutment by DIO CORPORATION

Reference Device

K171694, s-Clean TiN Coating Abutment by Dentis Co., Ltd.
K111364, HAPTITE Coating Implant System
K200099, s-Clean SQ-SL Implant System Mini

Indication for Use:

s-Clean Pre-Milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

No.	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
1	s-Clean SQ-SL Fixture	Ø5.8	Ø4.3
2		Ø6.8	Ø4.5

s-Clean Pre-Milled Abutment is intended for use with the s-Clean SQ-SL Fixtures in the chart. All digitally designed abutments for use with s-Clean Pre-Milled Abutment are intended to be manufactured at a Dentis validated milling center.

Device Description:
Patient-specific abutment is made from titanium alloy conforming to ASTM F136 titanium abutment to be used in fabricating patient-specific abutments. The subject abutments are indicated for cemented or "Screw-and Cement-Retained Prosthesis(SCRP)" restorations. Each patient-specific abutment is individually prescribed by the clinician.
The diameters of patient-specific abutment are 5.8, 6.8mm and two connection designs (Hex, Non-hex).

Patient-Specific Abutment is compatible with following Implant Systems:

Proprietary Name	Dentis s-Clean s-Line
Compatible Implants (K number)	K210134
Implant diameter size	5.8/6.8
Implant Interface Connection Type/Size (mm)	Internal Connection type/ 2.5
Type of Implant-Abutment Connection	Hex/Non-Hex

Patient-Specific Abutments are supplied with s-Clean abutment screw and provided non-sterile.

Patient-Specific Abutment design Limitation (Unit :mm)			
Model Name	Range (Diameter)	Range (Length)	Range (Angle)
DSCBA10H DSCBA14H DSCBA10N DSCBA14N	4.5-6.5	7.3-17.9	0-30º
DSCBM10H DSCBM14H DSCBM10N DSCBM14N	4.5-6.5	7.3-17.9	0-30º

Materials:

- S-Clean Pre-Milled Abutment and S-Clean Abutment Screw is fabricated from Ti-6Al-4V ELI (Conforming to ASTM Standard F136).

Summaries of Technology Characteristics

The subject device is substantially equivalent to the current cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

<Patient Specific Abutment>

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device</th></tr>
<tr><td>Applicant</td><td>Dentis Co., Ltd.</td><td>DIO Corporation</td></tr>
<tr><td>Trade Name</td><td>s-Clean Pre-Milled Abutment</td><td>DIO CAM/CAM Abutment</td></tr>
<tr><td>510(k) No.</td><td>K210362</td><td>K181037</td></tr>
<tr><td>Classification Name</td><td>Endosseous Dental Implant, Abutment (872.3630)</td><td>Endosseous Dental Implant, Abutment (872.3630)</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td></tr>
<tr><td>Class</td><td>II</td><td>II</td></tr>
<tr><td>Material</td><td>Ti-6AL-4V ELI (ASTM F136)</td><td>Ti-6AL-4V ELI (ASTM F136)</td></tr>
<tr><td>Diameter (mm)</td><td>CAD/CAM Patient-Specific Abutment
: 5.8/6.8</td><td>CAD/CAM Patient-Specific Abutment
: 3.0/3.3/3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0</td></tr>
<tr><td>Sterile</td><td>Steam Sterilization by user
(Provided Non-Sterile)</td><td>Steam Sterilization by user
(Provided Non-Sterile)</td></tr>
<tr><td>Type of Retention</td><td>Screw-retained or cement retained</td><td>Screw-retained or cement retained</td></tr>
<tr><td>Abutment Seat</td><td>Sits on Taper</td><td>Sits on Taper</td></tr>
<tr><td>Anatomical Site</td><td>Oral Cavity</td><td>Oral Cavity</td></tr>
<tr><td>Constructions</td><td>Machined</td><td>Machined</td></tr>
<tr><td>Indications For Use/
Intended Use</td><td>s-Clean Pre-Milled Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th></th><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>1</td><td rowspan="2">s-Clean SQ-SL Fixture</td><td>Ø5.8</td><td>Ø4.3</td></tr>
<tr><td>2</td><td>Ø6.8</td><td>Ø4.5</td></tr>
</table>
s-Clean Pre-Milled Abutment is intended for use with the s-Clean SQ-SL Fixtures in the chart. All digitally designed abutments for use with s-Clean Pre-Milled Abutment are intended to be manufactured at a Dentis validated milling center.</td><td>DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>UF(II) Narrow Implant System</td><td>3.0/3.3</td><td>3.0/3.3</td></tr>
<tr><td>UF Sub merged Implant System</td><td>3.8/4.0/4.5/5.0/5.5 /6.0/6.5/7.0</td><td>3.8/4.0/4.5/5.0/5.5 /6.0/6.5/7.0</td></tr>
<tr><td>UF(II) Implant System</td><td>3.8/4.0/4.5/5.0/5.5</td><td>3.8/4.0/4.5/5.0/5.5</td></tr>
</table></td></tr>
</table>

		Patient specific abutment is intended for use with the UF implant systems provided in the chart. All digitally designed abutments for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.
Substantial Equivalence Comparison	The subject patient specific abutment is substantially equivalent in designs, dimensions, material, indications, abutment seat, screw seat, anatomical site, connection, and technological characteristics with the identified primary predicate device. The patient specific abutment 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-food endosseous dental implants and endosseous dental implant abutments. The Indications for Use of the subject and primary predicate device are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing, and identification of reference device for compatible implant bodies. Both the predicate and subject devices are intended to be milled into patient specific abutments using CAD/CAM technology under the manufacturing control of the sponsor. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent.	

<s-Clean Abutment Screw>

	Subject Device	**Reference Device**
510(k) No.	K210362	K171694
Trade Name	s-Clean Pre-Milled Abutment	s-Clean TiN Coating Abutments
Manufacturer	Dentis Co,. Ltd	Dentis Co,. Ltd
Product Name	s-Clean Abutment Screw	s-Clean Abutment Screw
Diameter	ø2.32	ø2.32
Length	9.4	9.8
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterility	End-User Sterile	End-User Sterile
Brief Comparison	The Subject Device and Reference Device(K171694) has same manufacturer, Diameter, Indication for use, material and Sterility. Only length is different but this difference is not important factor for performance. Both devices are substantially equivalent.	

Non-Clinical Testing

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

- Fatigue Tests on subject device under the worst case scenario according to ISO 14801:2016

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

- Biocompatibility testing according to ISO 10993-1:2009 abutments referenced in K200099
- End User Sterilization Validation Test Report according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1 referenced in K111364

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

Non-clinical test data was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario, through fatigue testing. The result say that device performance was substantial equivalent.

Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion

The s-Clean Pre-Milled Abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, the s-Clean Pre-Milled Abutment and its predicates are substantially equivalent.