May 17, 2019

Surgident Co., Ltd.
% Peter Chung
Representative
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K173570
Trade/Device Name: SD Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 17, 2019
Received: April 19, 2019

Dear Peter Chung:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for Malvina Eydelman, M.D.
Director
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173570

Device Name
SD Abutment

Indications for Use *(Describe)*
SD Abutment is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit prosthetic restorations. SD Abutment is for single stage and two stage surgical procedures. This system is intended for delayed loading.

The SD Abutment is compatible with the following devices:

No.	Trade Name	Platform Diameters (mm)	Body Diameters (mm)	Lengths (mm)
1	s-Clean OneQ-SL Narrow Implant System	03.0	03.0	10, 12, 14
		03.3	03.3	
2	OneQ-SL s-Clean Implant System	03.7	03.5	7, 8, 10, 12, 14
		03.9	03.6	
		04.2	03.7	
		04.7	04.2	
		05.2	04.7	
		06.0	04.8	7, 8, 10, 12
		07.0	05.8	
		08.0	06.8	

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K173570 - 510(k) Summary [as required by 807.92(c)]

1. Applicant

a) Company: Surgident Co., Ltd.
b) Address: #209~210, Woolim Lion's Valley, 27, Dunchon-daero 457beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13219, Korea
c) Tel : +82-31-737-2875
d) Fax : +82-31-737-2876
e) President of Company: Mr. Duck Su Hur
f) Contact Person : Peter Chung
g) Contact Person Telephone: 412-687-3976
h) Contact Person Address: 300, Atwood Street, Pittsburgh, PA, 15213, USA
i) Preparation Date: May 17, 2019

2. Device Information

a) Trade Name : SD Abutment
b) Common Name : Endosseous Dental Implant Abutment
c) Classification Name : abutment, implant, dental, endosseous
d) Product Code : NHA
e) Regulation Number : 872.3630
f) Class of device : Class II
g) Panel : Dental

3. Primary Predicate

K131682, UD Implant System / MEDIMECCA Co., Ltd.

Reference Device

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

4. Device Description and Technological Characteristics

SD Abutment made of Ti-6A1-4V ELI alloy (ASTM F136) and/or Pure Titanium Gr4 (ASTM F67) is intended for use as an aid in single or multiple-unit prosthetic restorations. It consists of Healing Abutment, Solid Abutment, Dual Abutment, Dual Long Abutment, Angled Abutment (15˚ and 25°), Temporary Abutment and Abutment Screws. All abutments are supplied non-sterile and autoclaved by the end user. The abutments are to be used with the as followed fixtures:

No.	510k No.	Trade Name	Platform Diameters (mm)	Body Diameters (mm)	Lengths (mm)	Manufacturer
1	K161244	s-Clean OneQ-SL Narrow Implant System	03.0	03.0	10, 12, 14	Dentis Co., Ltd.
			03.3	03.3		
2	K153639	OneQ-SL s-Clean Implant System	03.7	03.5	7, 8, 10,	
			03.9	03.6		
			04.2	03.7		

			04.7	04.2	12, 14	
			05.2	04.7		
			06.0	04.8	7, 8, 10,	
			07.0	05.8	12	
			08.0	06.8		

5. Indication for Use

SD Abutment is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit prosthetic restorations. SD Abutment is for single stage and two stage surgical procedures. This system is intended for delayed loading.

The SD Abutment is compatible with the following devices:

No.	Trade Name	Platform Diameters (mm)	Body Diameters (mm)	Lengths (mm)
1	s-Clean OneQ-SL Narrow Implant System	03.0	03.0	10, 12, 14
		03.3	03.3	
2	OneQ-SL s-Clean Implant System	03.7	03.5	7, 8, 10, 12, 14
		03.9	03.6	
		04.2	03.7	
		04.7	04.2	
		05.2	04.7	
		06.0	04.8	7, 8, 10, 12
		07.0	05.8	
		08.0	06.8	

6. Performance Data

a) Physical Tests

No.	Test items	Results
1.	30° Compressive Loads	Equivalent to predicate devices
2.	Fatigue	
3.	Adaptation Accuracy	
4.	Torsional Breaking Force	
5.	Removal Torque Force	
6.	Adaptation Accuracy	
7.	Torsional Breaking Force	
8.	Removal Torque Force	
9.	30° Compressive Loads	
10.	Fatigue	
11.	Visual	
12.	Dimension	
13.	Package	

Reverse Engineering tolerance analysis was conducted on the original OEM 3rd party implant body, abutment, and abutment screw to ensure compatibility of the SD Abutment.

7. Predicate Device Comparison Table

The SD Abutment is substantially equivalent to previously marketed devices. The design features and sizing of the components were compared and the SD Abutment found to be substantially equivalent as the predicate device. The primary predicate includes a list of examples for single and multiple unit restorations whereas the subject device contains this information in the labeling for each specific abutment. Additionally, the primary predicate is dental abutments for the predicates own implant bodies whereas the subject device is a 3rd party abutment compatible. The inclusion of the specific compatible implant bodies, while different as compared to the primary predicate's Indications for Use, is necessary to adequately identify the indications for the subject device and the appropriate patient population. There are no significant differences between the SD Abutment and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to other devices in design, function, material and intended use.

<table>
<tr><td colspan="2"></td><td>SUBJECT Device</td><td>Primary PREDICATE Device
K131682</td></tr>
<tr><td colspan="2">Manufacturer</td><td>Surgident Co., Ltd.</td><td>MEDIMECCA Co., Ltd.</td></tr>
<tr><td colspan="2">Common Name</td><td>Endosseous Dental Implant Abutment</td><td>Endosseous Dental Implant</td></tr>
<tr><td colspan="2">Trade Name</td><td>SD Abutment</td><td>UD Implant System</td></tr>
<tr><td colspan="2">Indications for Use</td><td>SD Abutment is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit prosthetic restorations. SD Abutment is for single stage and two stage surgical procedures. This system is intended for delayed loading. The SD Abutment is compatible with the following devices:
<table>
<tr><th>No.</th><th>510k No.</th><th>Trade Name</th><th>Platform Diameters (mm)</th><th>Body Diameters (mm)</th><th>Lengths (mm)</th><th>Manufacturer</th></tr>
<tr><td rowspan="2">1</td><td rowspan="2">K161244</td><td rowspan="2">s-Clean OneQ-SL Narrow Implant System</td><td>Ø3.0</td><td>Ø3.0</td><td rowspan="2">10, 12, 14</td><td rowspan="10">Dentis Co., Ltd.</td></tr>
<tr><td>Ø3.3</td><td>Ø3.3</td></tr>
<tr><td rowspan="8">2</td><td rowspan="8">K153639</td><td rowspan="8">OneQ-SL s-Clean Implant System</td><td>Ø3.7</td><td>Ø3.5</td><td rowspan="5">7, 8, 10, 12, 14</td></tr>
<tr><td>Ø3.9</td><td>Ø3.6</td></tr>
<tr><td>Ø4.2</td><td>Ø3.7</td></tr>
<tr><td>Ø4.7</td><td>Ø4.2</td></tr>
<tr><td>Ø5.2</td><td>Ø4.7</td></tr>
<tr><td>Ø6.0</td><td>Ø4.8</td><td rowspan="3">7, 8, 10, 12</td></tr>
<tr><td>Ø7.0</td><td>Ø5.8</td></tr>
<tr><td>Ø8.0</td><td>Ø6.8</td></tr>
</table></td><td>UD Implant System intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. UD Implant System is for single stage and two stage surgical procedures. This system is intended for delayed lading.</td></tr>
<tr><td colspan="2">Components</td><td>Abutments</td><td>Fixtures and abutments</td></tr>
<tr><td>Healing</td><td>Type</td><td>Internal</td><td>Internal</td></tr>
</table>

Abutment	Diameter (mm)	4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5 mm, 7.5 mm, 8.5 mm	4.0 mm, 4.5 mm, 5.5 mm, 6.5 mm
Solid Abutment	Type	Internal	Internal
	Diameter (mm)	4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5 mm	4.0 mm, 4.5 mm, 5.5 mm, 6.5 mm
Dual Abutment	Type	Internal Hex, Internal Non-Hex	Internal Hex, Internal Non-Hex
	Diameter (mm)	4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5 mm	4.0 mm, 4.5 mm, 5.5 mm, 6.5 mm
Dual Long Abutment	Type	Internal Hex, Internal Non-Hex	Internal Hex, Internal Non-Hex
	Diameter (mm)	4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5 mm	4.0 mm, 4.5 mm, 5.5 mm, 6.5 mm
Angled Abutment	Type	Internal Hex, Internal Non-Hex	Internal Hex, Internal Non-Hex
	Diameter (mm)	4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5mm	4.5 mm, 5.5 mm
	Angulation	15°, 25°	15°, 25°
Temporary Abutment	Type	Internal Hex, Internal Non-Hex	Internal Hex, Internal Non-Hex
	Diameter (mm)	4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm, 6.5 mm	4.0 mm, 4.5 mm
Material		Ti-6Al-4V ELI (ASTM F136), or Titanium Grade 4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136), or Titanium Grade 4 (ASTM F67)
Physical testing performed		Test according to ISO 14801	Test according to ISO 14801
Biocompatibility		Biocompatible according to ISO 10993-1 (evaluated cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, implantation)	Biocompatible according to ISO 10993-1
Single Use		yes	yes
Sterilization method		The abutment is supplied non-sterile (Steam sterilization prior to use). Validation via ISO 17665-1 & ISO 17665-2	Gamma radiation

8. Conclusion

The SD 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-form endosseous dental implants and endosseous dental implant abutments".

The subject device and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of the titanium

alloys and have not the surface treatments. The subject and the predicate devices encompass the similar range of physical dimensions, including diameter and length of the implants. and diameter of the abutments.

Overall, the SD Abutment has the following similarities to the predicate device:

- has the same intended use.
- uses the same operating principle.
- incorporates the same basic design.
- incorporates the same material.

Based on the similarities, we conclude that the SD Abutment is substantially equivalent to the predicate device.