April 28, 2023

ARUM DENTISTRY Co., Ltd.
Boyeon Lim
Assistant Manager
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
SOUTH KOREA

Re: K223634
Trade/Device Name: Customized Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 5, 2023
Received: April 5, 2023

Dear Boyeon Lim:

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K223634

Device Name
Customized Abutment

Indications for Use *(Describe)*
ARUM Dentistry's Customized Abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Customized Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The Customized Abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.
Customized Abutments are compatible with the implant systems listed in the Compatibility Table:

Implant Platform compatibility	Restorative Platform diameter (mm)	Implant Body diameter (mm)
NB 1 SA Implant System	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5	3.8, 4.0, 4.15, 4.25, 4.5, 5.0

All digitally-designed Customized Abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

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.

510(K) Summary

Submitter

ARUM DENTISTRY Co., Ltd.
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Tel. +82-42-935-3644
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Date prepared: April 28, 2023

Device Information

- Trade Name: Customized Abutment
- Common Name: Abutment, Implant, Dental, Endosseous
- Classification Name: Endosseous dental implant abutment
- Primary Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II

Predicate Device Information

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following primary predicate and reference devices:

Primary Predicate

510(k)	Device Name	Company Name
K193425	Pre-Milled Blank	ARUM DENTISTRY Co., Ltd.

Reference Device

510(k)	Device Name	Company Name
K222131	NB 1 SA Implant System	ARUM DENTISTRY Co., Ltd.

Device Description:

Patient-specific abutment is made from Ti-6Al-4V Eli conforming to ASTM F136 to be used in fabricating patient-specific abutments. The subject devices 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 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm and two connection designs (Hex, Non-hex).

Patient-Specific Abutment is compatible with following Implant Systems:

Proprietary Name	NB 1 SA Implant System
Compatible Implants (K number)	K222131
Implant diameter size	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5
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 an abutment screw previous cleared device as K222131 and 7 newly designed screws and provided non-sterile.

Patient-specific abutment design parameters:

Parameter	Min (mm)	10 Ø Max (mm)	14 Ø Max (mm)
Total Height	6.0	16.0	16.0
Post Height for Single-Unit Restoration	4.0	13.0	13.0
Angle	0°	30°	30°
Wall Thickness	0.5	3.8	6.0
Diameter	Based on minimum wall thickness	9.9	13.9
Gingival Height	0.5	4.0	4.0

Indication for Use

ARUM Dentistry's Customized Abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Customized Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The Customized Abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.

Customized Abutments are compatible with the implant systems listed in the Compatibility Table:

Implant Platform compatibility	Restorative Platform diameter (mm)	Implant Body diameter (mm)
NB 1 SA Implant System	3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5	3.8, 4.0, 4.15, 4.25, 4.5, 5.0

All digitally-designed Customized Abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.

Materials:

Customized Abutment and Abutment screw are fabricated from Ti-6Al-4V Eli conforming to ASTM F136.

Summaries of Technological Characteristics & Substantial Equivalence Discussion

<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate</th></tr>
<tr><td>Manufacturer</td><td>ARUM DENTISTRY Co., Ltd.</td><td>ARUM DENTISTRY Co., Ltd.</td></tr>
<tr><td>Trade Name</td><td>Customized Abutment</td><td>Pre-Milled Blanks</td></tr>
<tr><td>510(k) Number</td><td>NA</td><td>K193425</td></tr>
<tr><td>Device Classification</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>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: 3.6, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5</td><td>CAD/CAM Patient-Specific Abutment: 5.8/6.8</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>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</td><td>ARUM Dentistry’s Customized Abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Customized Abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The Customized Abutment will be attached to a dental implant using the included ARUM Dentistry prosthetic screw.
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<tr><td>NB 1 SA Implant System</td><td>3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5</td><td>3.8, 4.0, 4.15, 4.25, 4.5, 5.0</td></tr>
</table>
</td><td>ARUM DENTISTRY’s Pre-Milled Blank abutments are intended for attachment to dental implants in order to provide support for customized prosthetic restorations. Pre-Milled Blank abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. The customized Pre-Milled Blank abutment will be attached to a dental implant using the included ARUM DENTISTRY prosthetic screw.
ARUM DENTISTRY’s Pre-Milled Blanks are compatible with the implant systems listed in the Compatibility Table:
<table>
<tr><th colspan="2">ARUM Pre-Milled Blanks</th><th rowspan="2">Implant Platform compatibility</th><th rowspan="2">Restorative Platform diameter (mm)</th><th rowspan="2">Implant Body diameter (mm)</th><th rowspan="2">Abutment Screw</th></tr>
<tr><th>Ø10 mm</th><th>Ø14 mm</th></tr>
</table>
</td></tr>
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<table>
<tr>
<td></td>
<td>All digitally-designed Customized Abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.</td>
<td>
<table>
<tr><td>CIHE037</td><td>CIHE038</td><td>NobelActive NP</td><td>3.5</td><td>3.5</td><td>CSTO001</td></tr>
<tr><td>CIHE039</td><td>CIHE040</td><td>NobelActive RP</td><td>3.9</td><td>4.3/5.0</td><td rowspan="2">CSTO002</td></tr>
<tr><td>CIHE135</td><td>CIHE136</td><td>NobelActive WP</td><td>5.1</td><td>5.5</td></tr>
</table>
All digitally-designed Pre-Milled Blank abutments are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.
</td>
</tr>
<tr>
<td>Abutment Design Parameters</td>
<td>Minimum wall thickness: 0.5 mm
Minimum post height: 4 mm
Maximum post height: 13 mm
Maximum angulation: 30 °
Maximum diameter: 13.9 mm
Minimum gingival height: 0.5 mm
Maximum gingival height: 4 mm</td>
<td>Minimum wall thickness: 0.5 mm
Minimum post height: 4 mm
Maximum post height: 13 mm
Maximum angulation: 30 °
Maximum diameter: 14 mm
Minimum gingival height: 0.5 mm
Maximum gingival height: 4 mm</td>
</tr>
<tr>
<td>Substantial Equivalence Comparison</td>
<td colspan="2">Except for the device name, reference/model numbers, the list of specific compatible platforms the Subject and Predicate devices have identical manufacturers, manufacturing processes, and Indications for Use. These differences do not change the intended use of the Subject and Predicate devices to provide support for single or multi-unit prosthetic restorations. Minor differences in abutment interface geometry due to compatible implant systems or restorative interface diameters do not introduce new risk nor change the intended use of the device to provide support for single and multi-unit prosthetic restorations. Overall, the Technological Characteristics, mode of operation and materials of the Subject device are substantially equivalent to that of the Predicate device.</td>
</tr>
</table>

MR Environment Condition

Non-clinical worst-case MRI Review was performed to evaluated the metallic. The Customized Abutment in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry 0., Jana G. Delfino, and Sunder Rajan. 'Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795)., based on the entire system including all variations (all compatible implant bodied, dental abutments and, fixation screws) and material composition. Rationale addressed parameters per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Non-Clinical Test Data

No need to perform any new additional non-clinical testing for the subject device since the subject device compared to predicate device are substantially equivalent in indications, fundamental technology, material and design. The predicate device may be leveraged for the subject devices because of using the same materials, manufacturing methods, and sterilization procedures. Although the dimensions are slightly different, it doesn't impact product's safety and effectiveness because the predicate device is the worst case based on the product's dimensional comparison analysis provided.

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

- Sterilization validation according to ISO 17665-1, ISO 17665-2, and ISO 14937 referenced in K193425.
- Biocompatibility according to ISO10993-5 and ANSI/AAMI ST72 referenced with K193425.

Non-clinical performance data submitted to demonstrate substantial equivalence included:

- Static and fatigue testing according to ISO 14801. No clinical data is included in this submission.

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

Equivalence to Marketed devices

Mechanical performance testing was performed according to ISO 14801. For each compatible implant line, worst-case constructs were subjected to static compression and compression fatigue testing. Minor differences in the designs, dimensions, sizes, or compatible implant lines among the subject device, the primary predicate device, and the reference devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence

because these differences are related to the compatible implant designs, or are mitigated by the mechanical performance testing.

Conclusion

The Customized 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 Customized Abutment and its predicates are substantially equivalent.