November 25, 2024

ARUM DENTISTRY Co., Ltd.
Choi Won-Yi
Official Correspondent
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
REPUBLIC OF KOREA

Re: K242245
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: July 31, 2024
Received: October 21, 2024

Dear Choi Won-Yi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K242245

Device Name
Customized Abutment

Indications for Use *(Describe)*
The Customized Abutments are intended use 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 abutment screw.
Patient-Specific Abutment is compatible with following Implant System:
1. Neodent Implant System -GM Line
/ Implant Diameter (mm): 3.5, 3.75, 4.0, 4.3, 5.0, 6.0/ Restorative Platform Diameter: 3.0
2. BioHorizons Tapered Internal Implant System
/ Implant Diameter (mm): 3.8, 4.6, 5.8/ Restorative Platform Diameter: 3.5, 4.5, 5.7
3. Astra Tech Implant System
/ Implant Diameter (mm): 3.5, 4.0, 4.5, 5.0/ Restorative Platform Diameter: 3.5, 4.0, 4.5, 5.0
4. 3i OSSEOTITE® Certain® Dental Implants
/ Implant Diameter (mm): 4.1, 5.0, 6.0/ Restorative Platform Diameter: 4.1, 5.0, 6.0
All digitally designed abutments for use with Customized Abutment are intended to be manufactured at an ARUM DENTISTRY 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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PRAStaff@fda.hhs.gov

"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."

510(K) Summary

Submitter

ARUM DENTISTRY Co., Ltd.
Won-Yi Choi
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
Republic of Korea
Email: arum_ra@arumdentistry.com
Tel. +82-42-935-3644
Fax. +82-42-935-3633

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
- Date Prepared: 11/25/2024

Predicate Devices:

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

Primary Predicate

- K223634, Customized Abutment by ARUM DENTISTRY Co., Ltd.

Reference Device

- K163194, Neodent Implant System - GM Line manufactured by JJGC Indústria e Comércio de Materiais Dentários SA
- K180536, Neodent Implant System - GM Line manufactured by JJGC Indústria e Comércio de Materiais Dentários S.A.
- K071638, BioHorizons Tapered Internal Implant System manufactured by BioHorizons Implant Systems, Inc.
- K091239, Astra Tech Implant System manufactured by Astra Tech AB
- K063341, 3i OSSEOTITE® Certain® Dental Implants manufactured by Biomet 3i

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 3.5, 3.75, 3.8, 4.0, 4.3, 4.5, 4.6, 5.0, 6.0 mm and Hex connection design.

Customized Abutments are compatible with the implant system listed in the following table:

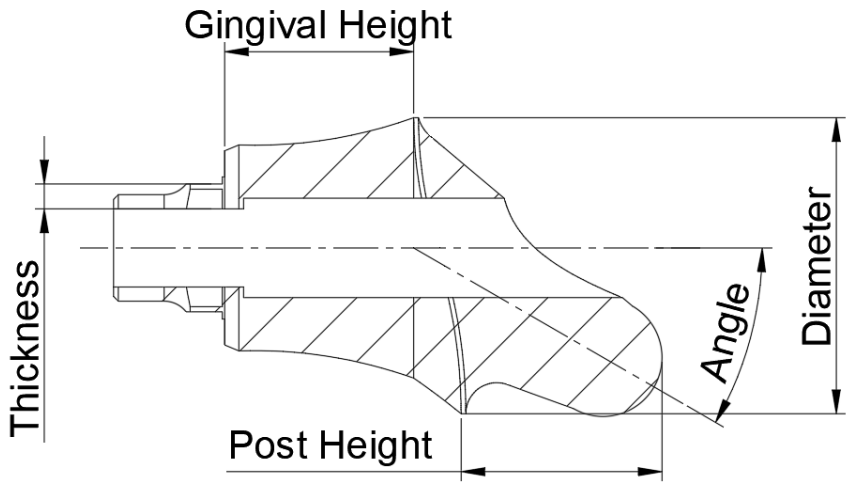
No.	Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
1	Neodent Implant System - GM Line	3.5, 3.75, 4.0, 4.3, 5.0, 6.0	3.0
2	BioHorizons Tapered Internal Implant System	3.8, 4.6, 5.8	3.5, 4.5, 5.7
3	Astra Tech Implant System	3.5, 4.0, 4.5, 5.0	3.5, 4.0, 4.5, 5.0
4	3i OSSEOTITE® Certain® Dental Implants	4.1, 5.0, 6.0	4.1, 5.0, 6.0

Customized abutments are supplied with an abutment and provided non-sterile.

Customized Abutment Compatibility Table:

Customized Abutment		Implant Platform compatibility	Restorative Platform diameter (mm)	Implant Body diameter (mm)	Abutment Screw
Ø10	Ø14				
CIHE023	CIHE024	Astra Tech Implant System	3.5, 4.0	3.5, 4.0	CSHE012
CIHE025	CIHE026	Astra Tech Implant System	4.5, 5.0	4.5, 5.0	CSHE013
CIHE053	CIHE054	BioHorizons Tapered Internal Implant System	3.5	3.8	CSHE020
CIHE055	CIHE056	BioHorizons Tapered Internal Implant System	4.5	4.6	CSHE020
CIHE057	CIHE058	BioHorizons Tapered Internal Implant System	5.7	5.8	CSHE020
CIHE095	CIHE096	3i OSSEOTITE® Certain® Dental Implants	4.1	4.1	CSHE035
CIHE097	CIHE098	3i OSSEOTITE® Certain® Dental Implants	5.0	5.0	CSHE035
CIHE099	CIHE100	3i OSSEOTITE® Certain® Dental Implants	6.0	6.0	CSHE035
CIHE201	CIHE202	Neodent Implant System - GM Line	3.0	3.5, 3.75, 4.0, 4.3, 5.0, 6.0	CSTO036

Patient-specific abutment design parameters:



Parameter	Min (mm)	10 Ø Max (mm)	14 Ø Max (mm)
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

※ **When machined at an angle of above 0°**

- Post Height for Single-Unit Restoration: 4.25mm
- Wall Thickness:0.5mm
- Diameter: 6.25
- Gingival Height: 4.0mm

Indication for Use

The Customized Abutments are intended use 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 abutment screw.

Patient-Specific Abutment is compatible with following Implant System:

1. Neodent Implant System -GM Line
   / Implant Diameter (mm): 3.5, 3.75, 4.0, 4.3, 5.0, 6.0/ Restorative Platform Diameter: 3.0
2. BioHorizons Tapered Internal Implant System
   / Implant Diameter (mm): 3.8, 4.6, 5.8/ Restorative Platform Diameter: 3.5, 4.5, 5.7
3. Astra Tech Implant System
   / Implant Diameter (mm): 3.5, 4.0, 4.5, 5.0/ Restorative Platform Diameter: 3.5, 4.0, 4.5, 5.0
4. 3i OSSEOTITE® Certain® Dental Implants
   / Implant Diameter (mm): 4.1, 5.0, 6.0/ Restorative Platform Diameter: 4.1, 5.0, 6.0

All digitally designed abutments for use with Customized Abutment are intended to be manufactured at an ARUM DENTISTRY validated milling center.

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>Customized Abutment</td></tr>
<tr><td>510(k) Number</td><td>K242245</td><td>K223634</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: 3.5, 3.75, 3.8, 4.0, 4.3, 4.5, 4.6, 5.0, 6.0 mm</td><td>CAD/CAM Patient-Specific Abutment: 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5</td></tr>
<tr><td>Abutment Design Parameters</td><td>
<table>
<tr><th>Parameter</th><th>Min (mm)</th><th>10 Ø Max (mm)</th><th>14 Ø Max (mm)</th></tr>
<tr><td>Total Height</td><td>6.0</td><td>16.0</td><td>16.0</td></tr>
<tr><td>Post Height for Single-Unit Restoration</td><td>4.0</td><td>13.0</td><td>13.0</td></tr>
<tr><td>Angle</td><td>0°</td><td>30°</td><td>30°</td></tr>
<tr><td>Wall Thickness</td><td>0.5</td><td>3.8</td><td>6.0</td></tr>
<tr><td>Diameter</td><td>Based on minimum wall thickness</td><td>9.9</td><td>13.9</td></tr>
<tr><td>Gingival Height</td><td>0.5</td><td>4.0</td><td>4.0</td></tr>
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<tr><td>Gingival Height</td><td>0.5</td><td>4.0</td><td>4.0</td></tr>
</table>
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<table>
<tr><td></td><td>※ When machined at an angle above 0°
- Post Height for Single – Unit Restoration: 5.25mm
- Wall Thickness: 0.5mm
- Diameter: 6.25
- Gingival Height: 4.0mm</td><td></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>The 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.
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<tr><th>No.</th><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>1</td><td>NB I 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>
All digitally-designed Customized Abutments are intended to be sent to an ARUM Dentistry-validated milling center for manufacture.</td></tr>
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<tr><td>3</td><td>Astra Tech Implant System</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>4</td><td>3i OSSEOTITE® Certain® Dental Implants</td><td>4.1, 5.0, 6.0</td><td>4.1, 5.0, 6.0</td></tr>
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All digitally-designed Customized abutments for use with Customized Abutment are intended to be manufactured at an ARUM DENTISTRY validated milling center.
</td><td></td></tr>
<tr><td>Substantial Equivalence Comparison</td><td colspan="2">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. The Indications for Use of the subject and primary predicate device are identical other than the compatible implant systems. This difference is mitigated by fatigue testing and the identification of reference devices 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 technical characteristics are accompanied by information that demonstrated the device is substantially equivalent to the predicate.</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.

Biocompatibility

Biocompatibility of Ti-6Al-4V Eli (ASTM F136) as leveraged from the reference ARUM DENTISTRY submission, K223634, using the same materials and manufacturing processes as the subject device.

Sterilization validation

The Customized Abutment delivered non-sterile to be end-user sterilized, the recommended sterilization has been validated according to ISO 17655-1 and to applicable recommendations in the FDA guidance document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015”. Reference device K223634 was leveraged for the subject devices because of using the same materials, manufacturing methods, and sterilization procedures.

Non-Clinical Test Data

Non-clinical performance data submitted to demonstrate substantial equivalence included: Reverse engineering of the OEM implant bodies, OEM abutments and OEM abutment screws to confirm compatibility; and static and fatigue testing according to ISO 14801. No clinical data is included in this submission.

Conclusion

Slight differences in the compatible implant system abutments available in the Subject and Predicate device systems does not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations.

The slight differences in the Technological Characteristics of the Subject and Predicate devices do not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations or introduce new risk or concerns of safety and effectiveness. Differences in Subject device abutment design parameters were validated with respect to intended use through Performance testing.

Overall, the Customized Abutment is substantially equivalent to the Predicate device.