September 09, 2025

Chengdu Besmile Medical Technology Co., Ltd.
Moushan Liu
Manager
No.9,Sec.2, Shengwucheng North Rd., Chengdu Tianfu
International Bio-Town, Shuangliu District, Chengdu, Sichuan
Chengdu, 610200
CHINA

Re: K242768
Trade/Device Name: Customized Abutment and Screw
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 21, 2025
Received: August 1, 2025

Dear Moushan Liu:

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,

Sherrill Lathrop Blitzer

for Andrew 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242768

Device Name
Customized Abutment and Screw

Indications for Use *(Describe)*

Customized Abutment and Screw is used as a complement component for dental implants placed in the jawbone after tooth loss, to connect, support and retain the restoration or implant superstructure. Customized Abutment and Screw is indicated for single unit restorations.

Customized Abutment and Screw is compatible with following Implant Systems:

No.	Implant System Compatibility	Implant Body Diameter(mm)	Platform Diameter(mm)
1	Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)	4.1,4.8	4.1,4.8
2	Straumann Bone Level NC 3.3 (composed of pure titanium)	3.3	3.3
3	Nobel Biocare Active NP3.5	3.5	3.5
4	Nobel Biocare Active RP4.3/5.0	4.3, 5.0	3.9, 3.9

All digitally designed abutments for use with Customized Abutment and Screw are intended to be manufactured at a BESMILE 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.

510(k) Summary for K242768

1 510(k) Submitter

Device Submitter: Chengdu Besmile Medical Technology Co., Ltd.
No.9,Sec.2, Shengwucheng North Rd., Chengdu Tianfu International Bio-Town, Shuangliu District, Chengdu, Sichuan 610200, P.R.China

Contact Person: Moushan Liu (Mr.)
Manager
Phone: +86-28-81501188
E-mail: xuetaohu@cdbesmile.com

2 Device

Trade Name of Device:	Customized Abutment and Screw
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	II
Product Code:	NHA
Classification Panel:	Dental
Date prepared:	April 28, 2025

3 Predicate Devices

Primary Predicate Device

K234112, Customized Abutment

Reference Devices

K193425, Pre-milled Blank

4 Device Description

The Customized Abutment and Screw is composed of two parts: the customized abutment and screw. Among them, the customized abutment is machined from Ti-6Al-4V titanium alloy material in accordance with ASTM F1472, and the screw is machined from Ti-6Al-4V ELI titanium alloy material in accordance with ASTM F136. And the surface of product is not modified. The lower part of the product has a fixed interface shape, and the upper part is machined according to the needs of the patient. In the process of dental implant surgery, as the upper structure of the implant, it is installed on the implant platform

anchored in the bone, which plays the role of supporting, retaining and stabilizing the prosthesis.

Customized Abutment and Screw is created via use of the Pre-milled Blank.

The information of the Implant Systems compatible with the product is detailed in Table 1.

Table 1 Compatible Implant Systems

No.	Model	Implant System Compatibility	Implant Body Diameter (mm)	Platform Diameter (mm)	510(k)	Implant Name	Company Name
1	QU-02	Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)	4.1,4.8	4.1,4.8	K140878	Straumann® Bone Level Tapered Implants	Straumann USA, LLC
2	QU-03	Straumann Bone Level NC 3.3 (composed of pure titanium)	3.3	3.3	K140878	Straumann® Bone Level Tapered Implants	Straumann USA, LLC
3	HE-04	Nobel Biocare Active NP3.5	3.5	3.5	K142260 K083205	NobelActive ® NobelActive 8.5 mm & 18.0 mm	Nobel Biocare AB
4	HE-05	Nobel Biocare Active RP4.3/5.0	4.3,5.0	3.9,3.9	K142260 K083205	NobelActive ® NobelActive 8.5 mm & 18.0 mm	Nobel Biocare AB

5 Intended Use

The product is used as a complement component for dental implants implanted in the jaw after tooth loss to attach, support and retain the prosthesis or implant superstructure.

6 Intended users

The target users of the product are hospitals, clinics or dental technicians. Users need to acquire relevant skills, knowledge and professional training before using these products.

7 Indications for use

Customized Abutment and Screw is used as a complement component for dental implants placed in the jawbone after tooth loss, to connect, support and retain the restoration or implant superstructure. Customized Abutment and Screw is indicated for single unit restorations.

Customized Abutment and Screw is compatible with following Implant Systems:

No.	Implant System Compatibility	Implant Body Diameter(mm)	Platform Diameter(mm)
1	Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)	4.1,4.8	4.1,4.8
2	Straumann Bone Level NC 3.3 (composed of pure titanium)	3.3	3.3
3	Nobel Biocare Active NP3.5	3.5	3.5
4	Nobel Biocare Active RP4.3/5.0	4.3, 5.0	3.9, 3.9

All digitally designed abutments for use with Customized Abutment and Screw are intended to be manufactured at a BESMILE validated milling center.

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8 Substantial Equivalence Discussion

Table 2 Comparison of Indications for Use

<table>
<tr><th>Parameter</th><th>Subject Device
Customized Abutment and Screw
K242768</th><th>Primary Predicate Device
Customized Abutment
K234112</th><th>Reference Device
Pre-milled Blank
K193425</th></tr>
<tr><td>Indications for Use</td><td>Customized Abutment and Screw is used as a complement component for dental implants placed in the jawbone after tooth loss, to connect, support and retain the restoration or implant superstructure. Customized Abutment and Screw is indicated for single unit restorations.
Customized Abutment and Screw is compatible with following Implant Systems:
<table>
<tr><th>No.</th><th>Implant System Compatibility</th><th>Implant Body Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>1</td><td>Straumann Bone Level RC 4.1, RC 4.8 (composed of pure titanium)</td><td>4.1,4.8</td><td>4.1,4.8</td></tr>
</table></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.
<table>
<tr><th>No.</th><th>Proprietary Name</th><th>Implant diameter size (mm)</th><th>Restorative Platform diameter (mm)</th></tr>
<tr><td>1</td><td>Zimmer Tapered Screw-vent®</td><td>3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>2</td><td>Straumann® Bone Level Tapered Implant</td><td>3.3, 4.1, 4.8</td><td>3.1, 3.7, 4.4</td></tr>
</table>
All digitally designed abutments for use with</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:
Compatibility Table
<table>
<tr><td>ARUM Pre-Milled Blank</td><td>Implant Platfor</td><td>Restorative Platfor</td><td>Implant Body</td><td>Abutment Scre</td></tr>
</table></td></tr>
</table>

<table>
<tr>
<td></td>
<td>
<table>
<tr><td>2</td><td>Straumann Bone Level NC 3.3 (composed of pure titanium)</td><td>3.3</td><td>3.3</td></tr>
<tr><td>3</td><td>Nobel Biocare Active NP3.5</td><td>3.5</td><td>3.5</td></tr>
<tr><td>4</td><td>Nobel Biocare Active RP4.3/5.0</td><td>4.3,5.0</td><td>3.9, 3.9</td></tr>
</table>
All digitally designed abutments for use with Customized Abutment and Screw are intended to be manufactured at a BESMILE validated milling center.
</td>
<td>Customized Abutment are intended to be manufactured at an ARUM DENTISTRY validated milling center.</td>
<td>
<table>
<tr><td>Ø10 mm</td><td>Ø14 mm</td><td>m compatibility</td><td>m diameter [mm]</td><td>diameter [mm]</td><td>w</td></tr>
<tr><td>CIHE 037</td><td>CIHE 038</td><td>Nobel Active NP</td><td>3.5</td><td>3.5</td><td>CSTO001</td></tr>
<tr><td>CIHE 039</td><td>CIHE 040</td><td>Nobel Active RP</td><td>3.9</td><td>4.3/5.0</td><td>CSTO002</td></tr>
<tr><td>CIHE 135</td><td>CIHE 136</td><td>Nobel Active WP</td><td>5.1</td><td>5.5</td><td></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>
</table>

Discussion on differences in substantive equivalence:

The Subject Device is compared with the Primary Predicate Device, the Primary Predicate Device can be used for single and multiple teeth, and the Subject Device is used for single teeth only. Therefore, the intended use of the Subject Device is included within the intended use of the Primary Predicate Device.

The difference between the subject device and Primary Predicate Device is the compatible implant bodies. This comparison is for similarity of device, not for implant's compatibility.

The Subject Device, in contrast to the Reference Device (K193425) which can be used for single and multiple tooth restorations, is used only for single tooth restorations. Therefore, the intended use of the Subject Device is within the intended use of the Reference Device.

Table 3 Technological Characteristics' Comparison				
Parameter	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Discussion**
K number	K242768	K234112	K193425	/
Trade Name	Customized Abutment and Screw	Customized Abutment	Pre-milled Blank	/
Manufacturer	Chengdu Besmile Medical Technology Co., Ltd.	ARUM DENTISTRY Co., Ltd.	ARUM Dentistry Co., Ltd.	/
Product Code(s)	NHA	NHA	NHA	Identical
Device Class	Class II	Class II	Class II	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Categorization by nature of body contact	Implant medical device: Tissue/bone-Medical devices principally contacting bone	Implant medical device: Tissue/bone-Medical devices principally contacting bone	Implant medical device: Tissue/bone-Medical devices principally contacting bone	Identical
Contact duration	Long-term exposure	Long-term exposure	Long-term exposure	Identical

categories				
Restoration	Single-unit	Single-unit, Multi-unit	Single-unit & Multi-Unit	Different Comment 1
Diameter	4.0-6.5mm	3.3-6.0mm	/	Similar Comment 2
Transgingival height	1-5mm	0.5-4.0mm	0.5-4.0mm	
Post height	4-12mm	4-13mm	4-13mm	
Abutment Angle	0-30°	0-30°	0-30°	
Wall thickness	≧0.5mm	0.5-6.0mm	≧0.5mm	Identical
Material	Ti-6Al-4V (ASTM F1472) Ti-6Al-4VELI (ASTM F136)	Ti-6AL-4V ELI (ASTM F136)	Titanium Ti-6Al-4V ELI	Similar Comment 3
Surface Treatment	Untreated	/	Untreated	Identical
Connection type	Internal connection	/	Internal connection	Identical
Reusable	No, single-use	No, single-use	No, single-use	Identical
Delivery	Non sterile	Non sterile	Non sterile	Identical
Sterilization method	Steam Sterilization	Steam Sterilization	Steam Sterilization	Identical

Comment 1

The Subject Device is used for single-unit restorations only, and the Primary Predicate Device (K234112) can be used for single-unit and multi-unit restorations. The Primary Predicate Device override the Subject Device.

The difference do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

The Subject Device, in contrast to the Reference Device (K193425) which can be used for single and multiple tooth restorations, is used only for single tooth restorations. Therefore, the type of restoration for the Subject Device is within the restoration type of the Reference Device.

Comment 2

Subject Device Diameter ranges from 4.0-6.5mm, Primary Predicate Device(K234112) ranges from 3.3-6.0mm.

Transgingival height range of Subject Device(1-5mm) exceeds the Primary Predicate Device((0.5-4.0mm).

Primary Predicate Device's post height (4-13mm) contains post height range of the Subject Device (4-12mm).

Primary Predicate Device and Subject Device have the same abutment angle range.

There are slight differences in Abutment Design Parameters for the Subject Device, Primary Predicate Device. According to ISO 14801: 2016 *Dentistry - Implants - Dynamic loading test for endosseous dental implants*, the worst-case static fatigue test and dynamic fatigue test were performed on dental implants connected with the Subject Device. The test results show that the worst-case scenario of the Subject Device has sufficient strength for the intended clinical application. Therefore, slight differences in Abutment Design Parameters do not affect the intended use and do not adversely affect the safety and effectiveness of the Subject Device.

Compared with Reference Device (K193425), Subject Device has the different post height and transgingival heigh. Subject Device is within the post height range of Reference Device; Subject Device is outside the transgingival height range of Reference Device.

Abutments made of Pre-milled Blank are designed according to the patient's condition. We performed static fatigue tests and dynamic fatigue tests in accordance with ISO 14801:2016 *Dentistry - Implants - Dynamic loading test for endosseous dental implants*, static

fatigue test and dynamic fatigue test for the worst-case scenario. The test results show that the worst-case scenario of the Subject Device has sufficient strength for the intended clinical application.
Therefore, differences in Abutment Design Parameters do not change the intended use of the device and do not raise safety effectiveness issues.

Comment 3
The material of Subject Device abutment is Ti-6AL-4V, screw's material is Ti-6AL-4V ELI. The material of Primary Predicate Device(K234112) is Ti-6AL-4V ELI.
Both Ti-6AL-4V and Ti-6AL-4V ELI are common fabrication materials for abutment and implant with a long history of clinical use. According to ISO 14801: 2016 *Dentistry - Implants - Dynamic loading test for endosseous dental implants*, the worst-case static fatigue test and dynamic fatigue test were performed on dental implants connected with Subject Device. The test results show that the worst-case scenario of the Subject Device has sufficient strength for the intended clinical application. Therefore, Subject Device is made of the same material as the commercially available products, both of which are titanium alloys, so the materials do not adversely affect the safety and effectiveness of the Subject Device.

The abutment material of Subject Device is Ti-6AL-4V, screw's material is Ti-6AL-4V Eli, and Reference Device's (K193425) material is Ti-6AL-4V Eli.
Both Ti-6AL-4V and Ti-6AL-4V ELI are common fabrication materials for abutment and implant with a long history of clinical use. According to ISO 14801:2016 *Dentistry - Implants - Dynamic loading test for endosseous dental implants*, we performed the static fatigue testing and dynamic fatigue testing of worst-case abutments made of Subject Device. The test results indicate that the worst case of the Subject Device has sufficient strength for the intended clinical application.
Therefore, differences in materials do not change the intended use of the device and do not raise questions of safety and effectiveness.

Substantial Equivalence Conclusion：

The corresponding data show that the technical characteristics of the Subject Device and the Predicate Device(K234112) are basically identical. The minor difference between the Subject Device and the Predicate Device(K234112) is the difference in the compatible implant systems, but we compare the similarity of the devices rather than the compatibility of the implant systems, so it does not affect the intended use.

We have also analyzed the compatibility of our products with the OEM implants, and the results show that our products are compatible with the OEM implants, and we have taken effective measures to ensure that our products maintain continuous compatibility with the appropriate OEM implants.

Based on the above, we consider the Subject Device and the Predicate Device(K234112) to be essentially equivalent.

Subject Device is as safe and effective as the reference device (K193425) when used as instructed by knowledgeable and trained dental personnel. The product is identical to its reference device (K193425) concerning to the indications for use.

The corresponding data show that the technical characteristics of the Subject Device and the reference device (K193425) are basically identical.The minor difference between the Subject Device and the reference device (K193425) is the difference in the compatible implant systems. However, we compare the similarity of the devices, not the compatibility of the implant systems, so it does not affect the intended use.

Based on the above points, we consider that Subject Device is essentially equivalent to reference device (K193425).

9 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

9.1 Non-Clinical Performance Data (Bench)

Performance testing was conducted on the Subject Device according to the technical specification, and the test results meet the standard.

9.2 Engineering Analysis

Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible OEM implant body, OEM abutment, and OEM fixation screw. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate devices.

9.3 Fatigue Testing

According to the FDA guidance document: *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* and ISO 14801 *Dentistry - Implants - Dynamic loading test for endosseous dental implants*, the static fatigue tests and dynamic fatigue tests were performed on the worst case for each implant which is compatible with, of the Subject Device. The test results show that the Subject Device has sufficient strength for the intended clinical application.

9.4 Biocompatibility Testing

We conducted a biocompatibility evaluation in accordance with ISO 10993-1 Medical devices -Biological evaluation - Part 1: Evaluation and testing in the context of risk management.
Biological test results comply with ISO 10993 series standards.

9.5 Sterilization validation

Validation of moist heat sterilization showed that it could achieve a sterility assurance level (10^{-6}).

9.6 Surface cleanliness analysis

Scanning electron microscopy (SEM) and Energy dispersive X-ray spectroscopy (EDS) confirmed that the Subject Device surface was clean, with no chemical residues or particles remaining.

9.7 MR Environment Condition

Non-Clinical worst-case MRI review was performed to evaluated the Subject Device in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan. (2019). Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. Journal of Testing and Evaluation 49.2, 783795), based on the entire system including all variations 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.

9.8 Shelf-life

The shelf-life is not applicable because of low likelihood of time-dependent product degradation.

10 Clinical Test Conclusion

No clinical study is included in this submission.

11 Conclusion

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials.

The documentation submitted in this premarket notification demonstrates that the subject devices are substantially equivalent to the primary predicate and reference devices.