



September 23, 2026

Unidental Co., Ltd.
Sungjoon Yang
CEO
#D-613, Gm Technopark
60 Haan-Ro
Gwangmyeong-Si, 14322
REPUBLIC OF KOREA

Re: K262207

Trade/Device Name: Cemented Plus Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 24, 2026
Received: July 29, 2026

Dear Sungjoon Yang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K262207

?

Please provide the device trade name(s).

?

Cemented Plus Abutment

Please provide your Indications for Use below.

?

The Cemented Plus Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of prosthetic restorations including single crowns and fixed partial dentures.

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	UNIDENTAL CO., LTD.
Applicant Address	#D-613, GM Technopark 60 Haan-ro Gwangmyeong-si 14322 Korea, Republic of
Applicant Contact Telephone	82-10-3716-4393
Applicant Contact	Mr. Sungjoon Yang
Applicant Contact Email	unidentalkorea@gmail.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Cemented Plus Abutment
Common Name	Endosseous dental implant abutment
Classification Name	Abutment, Implant, Dental, Endosseous
Regulation Number	872.3630
Product Code(s)	NHA

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221315	UNIDENTAL Symphony Implant System	NHA

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Cemented Plus Abutment is a non-sterile, single-use dental abutment that is intended to be sterilized by the end-user prior to placement. The Cemented Plus Abutment is intended for use with the following compatible Symphony 2 Fixture implant bodies cleared under the primary predicate K221315: US2-3308RN18, US2-3310RN18, US2-3312RN18, US2-3314RN18, US2-4107RN18, US2-4108RN18, US2-4110RN18, US2-4112RN18, US2-4114RN18, US2-4807RN18, US2-4808RN18, US2-4810RN18, US2-4812RN18, US2-4814RN18, US2-3308RN28, US2-3310RN28, US2-3312RN28, US2-3314RN28, US2-4107RN28, US2-4108RN28, US2-4110RN28, US2-4112RN28, US2-4114RN28, US2-4807RN28, US2-4808RN28, US2-4810RN28, US2-4812RN28, and US2-4814RN28. The device is manufactured from titanium alloy (Ti-6Al-4V ELI) and is available in multiple sizes to accommodate different clinical requirements. It is connected to the implant fixture using an abutment screw to provide a stable connection for prosthetic restoration. The corresponding abutment screw (US2CMP-SC) is manufactured from Ti-6Al-4V ELI (Grade 5 ELI) titanium alloy. The device has the same fundamental scientific technology as the predicate device. The dimensional modifications include the addition of a 2.0 mm gingival collar to the subject device. These dimensional modifications do not affect the intended use, technological characteristics, or fundamental operating principles.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Cemented Plus Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of prosthetic restorations including single crowns and fixed partial dentures.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject device has the same intended use as the primary predicate device. The differences in the Indications for Use language are due to the subject device being limited to the Cemented Plus Abutment, whereas the primary predicate encompasses the broader UNIDENTAL Symphony Implant System. These differences in wording do not represent a different intended use.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device has the same fundamental technological characteristics as the primary predicate device, including the intended use, titanium alloy material family (Ti-6Al-4V ELI), Symphony 2 implant-abutment connection, screw fixation, and principle of operation. The differences are limited to dimensional design features. Specifically, the subject Cemented Plus Abutment has a maximum coronal diameter of 5.5 mm, an overall length of approximately 9.75 mm, a 4.8 mm implant-platform region, a 3.1 mm octagonal connection feature, and a 2.0 mm gingival collar. In comparison, the cleared Symphony 2 cemented abutments under K221315 include diameters of approximately 3.5, 3.55, and 4.3 mm and overall lengths of approximately 6.7, 8.2, and 8.4 mm, while maintaining the same 3.1 mm octagonal connection feature. These dimensional modifications do not change the material, connection feature, fixation method, or principle of operation and do not raise different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-clinical evidence supporting substantial equivalence includes mechanical performance testing as well as fatigue, biocompatibility, and validated end-user sterilization labeling leveraged from the primary predicate K221315. The subject device maintains the same material family, implant-abutment connection, screw fixation, and fundamental design principles as the primary predicate. The dimensional modifications, including the addition of a 2.0 mm gingival collar, do not create a new worst-case configuration requiring additional fatigue, biocompatibility, or sterilization validation. The available evidence supports that these dimensional modifications do not raise different questions of safety or effectiveness.

Not Applicable

The submitted nonclinical testing demonstrates that the subject device is as safe and effective as the predicate device K221315 and supports a determination of substantial equivalence.