March 19, 2026

DiaDent Group International
Jin An
RA team
16, Osongsaengmyeong 4-Ro, Osong-Eup, Heungdeok-Gu
Cheongju-Si, 28186
REPUBLIC OF KOREA

Re: K254112
Trade/Device Name: Dia-X Sil Bite
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: December 16, 2025
Received: December 19, 2025

Dear Jin An:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
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DHT1B: Division of Dental and
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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.

Submission Number *(if known)*

K254112

Device Name

Dia-X Sil Bite

Indications for Use *(Describe)*

- Indicated for bite registration in prosthodontics, orthodontics, and implantology.
- Used for recording the occlusal relationship to aid in the fabrication of crowns, bridges, dentures, and orthodontic appliances.
- Suitable of occlusal analysis and adjustment in clinical dental procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) substantial equivalence information is submitted in accordance with the requirements of 21 CFR 807.92.

1. Application Information

510(k) Number	K254112
Date Prepared	Mar 19, 2026
Company Name and Address	DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea
Contact Person	Byung Chul Kim Quality Assurance Manager Phone: +82-43-266-2315 FAX: +82-43-235-2315 Email: diadent68@diadent.co.kr

2. Device Information

Device Type	Material, Impression
Regulation Description	Impression material
Review Panel	Dental
Regulation Number	21 CFR 872.3660
Product Code	ELW
Device Class	II
Device Name	Dia-X Sil Bite

3. Primary Predicate Device

510(k) Number	K882690
Applicant	3M ESPE
Device Name	Imprint Bite
Regulation Number	21 CFR 872.3660
Product Code	ELW
Device Class	II

4. Device Description

Dia-X Sil Bite is vinyl polysiloxane (VPS) – based bite registration material designed for occlusal capture. Classified as Type B under ISO 4823 standards.

No.	Model Name	Composition
1	Dia-X Sil Bite A Type	Dia-X Sil Bite 50ml Cartridge 1ea
2	Dia-X Sil Bite C Type	Dia-X Sil Bite 50ml Cartridge 2ea
3	Dia-X Sil Bite E Type	Dia-X Sil Bite 50ml Cartridge 4ea + Mixing Tip 10ea
4	Dia-X Sil Bite G type	Dia-X Sil Bite 50ml Cartridge 10ea

5. Indications for Use
- Indicated for bite registration in prosthodontics, orthodontics, and implantology.
- Used for recording the occlusal relationship to aid in the fabrication of crowns, bridges, dentures, and orthodontic appliances.
- Suitable of occlusal analysis and adjustment in clinical dental procedures.

6. Technological Characteristics
The subject device, Dia-X Sil Bite has similar characteristics to the primary predicate device, Imprint Bite.

[Comparison table]

	Subject Device	Predicate Device	Discuss
510(k) Number	-	K882690	-
Product Code	ELW	ELW	Equivalent
Device Class	II	II	Equivalent
Manufacturer	DiaDent Group International	3M ESPE	-
Device Name	Dia-X Sil Bite	Imprint Bite	-
Intended Use	to obtain the structure of a patient's teeth and gums	to obtain the structure of a patient's teeth and gums	Equivalent
Raw Materials	- Silicone Base	- Silicone Base	* See the below table.
Principle of operation	It is an elastic occlusal recording material in a convenient cartridge form designed to harden when in contact with oral moisture. It is used to capture precise occlusal relationships	It is an elastic occlusal recording material in a convenient cartridge form designed to harden when in contact with oral moisture. It is used to capture precise occlusal relationships.	Equivalent
Performance Standard Conformance	Conformed ISO 4823	Conformed ISO 4823	Equivalent
Physical and Mechanical properties	- Setting time - Working time - Hardness	- Setting time - Working time - Hardness	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Equivalent
Use	Prescription / Hospital	Prescription / Hospital	Equivalent
Period of use	Permanent	Permanent	Equivalent
Sterility	Non-sterile	Non-sterile	Equivalent
Shelf-life	2 years	2 years	Equivalent

* Difference table

Subject Device	Predicate Device	Discussion
- Silicone Base	- Silicone Base	Both this device and the existing device contain the main ingredient, silicone base. Through the biocompatibility test results, the difference does not raise any issue of safety and effectiveness.

7. Non-Clinical Performance Data
The performance and biological tests were conducted on the subject device; Dia-X Sil Bite according to the following standards.

ISO 4823:2021, Dentistry — Elastomeric impression and bite registration materials
ISO 7405:2018, Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation

To demonstrate equivalence in the biological safety of the subject device, the following specific biocompatibility tests were performed:

In vitro Cytotoxicity Test (per ISO 10993-5:2009)
Skin Sensitization Test (per ISO 10993-10:2021)
Oral Mucosa Irritation Test (per ISO 10993-23:2021)

The test results corresponded to the requirements of standards. Therefore, the subject device is substantially equivalent to the predicate device.

8. Clinical Performance Data
No clinical data was collected or provided to support substantial equivalence between the subject and predicate device.

9. Conclusions
Based on the above information and all data provided in this submission, the subject device is substantially equivalent to the legally marketed device identified in this submission.