

**K254112 Dia-X Sil Bite**Mar 19, 2026  
90 days to decisionK254112 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k254112/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Dec 19, 2025
Decision date	Mar 19, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>DiaDent Group International</b>
Location	Chungcheong Buk-Do, KR
Contact	Jin An
510(k) history	19 submissions · 19 cleared · 2013-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254112/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026