

**K260485 Any-Etch**May 14, 2026  
90 days to decisionK260485 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k260485/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Feb 13, 2026
Decision date	May 14, 2026
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mediclus Co., Ltd.</b>
Location	Cheongju-Si, KR
Contact	Ku Da Hyeon
510(k) history	13 submissions · 13 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260485/> 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 June 5, 2026