

K232978 DX. Bond V Dental Bonding AdhesiveSep 22, 2023
1 days to decisionK232978 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k232978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Sep 21, 2023
Decision date	Sep 22, 2023
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sino-Dentex Co., Ltd.
Location	Saint Paul, MN, US
Contact	Pengtao Yan
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232978/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026