

K221450 Phosphoric Acid Etching GelSep 12, 2022
117 days to decisionK221450 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k221450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 18, 2022
Decision date	Sep 12, 2022
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rizhao Huge Biomaterials Company, Ltd.
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	13 submissions · 13 cleared · 2020-2025

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