

K210945 Ultra SEPJul 8, 2021
100 days to decisionK210945 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k210945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Mar 30, 2021
Decision date	Jul 8, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reliance Orthodontic Products, Inc.
Location	Itasca, IL, US
Contact	Christine Cook
510(k) history	32 submissions · 32 cleared · 1988-2021

REGULATORY CONSULTANT

Consulting firm	Cook Device Solutions
Contact	Brian Dean

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210945/> 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 14, 2026