FDA 510(k) Premarket Notification

K210945 Ultra SEP

CLEARED

Jul 8, 2021
100 days to decision

K210945 · 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