

K213093 STEP-1 PumEtchJan 28, 2022
126 days to decisionK213093 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k213093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Sep 24, 2021
Decision date	Jan 28, 2022
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rounding Third, LLC
Location	Centennial, CO, US
Contact	Thomas Macari
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Qrs Solutions, LLC
Contact	Adrienne Von Foller

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

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