

K221033 UniPrime A, UniPrime E, UniPrime E/CJul 6, 2022
90 days to decisionK221033 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k221033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Apr 7, 2022
Decision date	Jul 6, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	S&C Polymer Silicon- Und Composite Spezialit?ten GmbH
Location	Elmshorn, DE
Contact	Christian Böttcher
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221033/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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