

**K210804 Adhese Universal DC, Cention Primer**Jun 7, 2022  
447 days to decisionK210804 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k210804/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Mar 17, 2021
Decision date	Jun 7, 2022
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ivoclar Vivadent, AG</b>
Location	Amherst, NY, US
Contact	Sandra Cakebread
510(k) history	31 submissions · 31 cleared · 2004-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ivoclar Vivadent, Inc.</b>
Contact	Robert Streber

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210804/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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