

**K191524 Visalys Tooth Primer**Sep 29, 2019  
111 days to decisionK191524 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k191524/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jun 10, 2019
Decision date	Sep 29, 2019
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Kettenbach GmbH &amp; Co. KG</b>
Location	Eschenburg, DE
Contact	Katja Simon
510(k) history	13 submissions · 13 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191524/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026