

**K190571 StoneBite and StoneBite scan**Nov 7, 2019  
246 days to decisionK190571 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k190571/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Impression (ELW)
Date received	Mar 6, 2019
Decision date	Nov 7, 2019
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dreve Dentamid GmbH</b>
Location	Unna, DE
Contact	Reiner Altmann
510(k) history	6 submissions · 6 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190571/> 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 25, 2026