

**K191320 Slow Wave DS8**Oct 2, 2020  
506 days to decisionK191320 · Product code: **LQZ** · Dental  
Source: <https://www.510kdatabase.net/k191320/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Jaw Repositioning (LQZ)
Date received	May 15, 2019
Decision date	Oct 2, 2020
Days to decision	506 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Slow Wave, Inc.</b>
Location	Spicewood, TX, US
Contact	Wayne R. Wagner
510(k) history	2 submissions · 2 cleared · 2020-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191320/> 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