

**K190359 Sonendo GentleWave System**Mar 16, 2019  
29 days to decisionK190359 · Product code: **ELC** · Dental  
Source: <https://www.510kdatabase.net/k190359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Scaler, Ultrasonic (ELC)
Date received	Feb 15, 2019
Decision date	Mar 16, 2019
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sonendo, Inc.</b>
Location	Laguna Hills, CA, US
Contact	Eric Simon
510(k) history	9 submissions · 9 cleared · 2013-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190359/> 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 26, 2026