

**K160905 Sonendo GentleWave System**Jun 3, 2016  
63 days to decisionK160905 · Product code: **ELC** · Dental  
Source: <https://www.510kdatabase.net/k160905/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Scaler, Ultrasonic (ELC)
Date received	Apr 1, 2016
Decision date	Jun 3, 2016
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160905/> 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