

**K162392 Avazzia**May 12, 2017  
259 days to decisionK162392 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k162392/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 26, 2016
Decision date	May 12, 2017
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avazzia, Inc.</b>
Location	Dallas, TX, US
Contact	TAMMY LAHUTSKY
510(k) history	4 submissions · 4 cleared · 2007-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162392/> 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