

**K251909 NeurotriS (SX2500)**Sep 3, 2025  
75 days to decisionK251909 · Product code: **NFO** · Neurology  
Source: <https://www.510kdatabase.net/k251909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Jun 20, 2025
Decision date	Sep 3, 2025
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NeurotriS (SX3800)

**APPLICANT**

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Company	<b>A-1 Engineering</b>
Location	Irvine, CA, US
Contact	Anthony Picciano
510(k) history	2 submissions · 2 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251909/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026