

**K251210 Ampa One System (AMPA-001)**Jun 27, 2025  
70 days to decisionK251210 · Product code: **OBP** · Neurology  
Source: <https://www.510kdatabase.net/k251210/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transcranial Magnetic Stimulator (OBP)
Date received	Apr 18, 2025
Decision date	Jun 27, 2025
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neuromodulatory Devices &amp; Applications</b>
Location	San Diego, CA, US
Contact	Don Vaughn
510(k) history	2 submissions · 2 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Avio Medtech Consulting</b>
Contact	Matthieu Kirkland

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251210/> 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 13, 2026