

**K241737 Sway System Sports Plus**Feb 15, 2025  
243 days to decisionK241737 · Product code: **POM** · Neurology  
Source: <https://www.510kdatabase.net/k241737/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Cognitive Assessment Aid For Concussion (POM)
Date received	Jun 17, 2024
Decision date	Feb 15, 2025
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sway Medical, Inc.</b>
Location	Tulsa, OK, US
Contact	Alex Pettigrew
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Steurer Consulting Group, LLC</b>
Contact	Robert Steurer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241737/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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