

**K241957 Talee, Talee PostOp**Aug 30, 2024  
58 days to decisionK241957 · Product code: **MVA** · Neurology  
Source: <https://www.510kdatabase.net/k241957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Jul 3, 2024
Decision date	Aug 30, 2024
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Invent Medical USA, LLC</b>
Location	Warminster, PA, US
Contact	Jiri Rosicky
510(k) history	3 submissions · 3 cleared · 2022-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241957/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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