

K220681 Talee, Talee PostOPSep 22, 2022
198 days to decisionK220681 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k220681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Mar 8, 2022
Decision date	Sep 22, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220681/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026