

K213587 MyCRO BandJun 9, 2022
209 days to decisionK213587 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k213587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Nov 12, 2021
Decision date	Jun 9, 2022
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Otto Bock Healthcare LP
Location	Minneapolis, MN, US
Contact	Caleb Beck
510(k) history	17 submissions · 17 cleared · 2003-2022

REGULATORY CONSULTANT

Consulting firm	Strategic Quality Solutions, LLC
Contact	Adrienne von Foller

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213587/> 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