

**K201426 MyCRO Band**Mar 26, 2021  
301 days to decisionK201426 · Product code: **MVA** · Neurology  
Source: <https://www.510kdatabase.net/k201426/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	May 29, 2020
Decision date	Mar 26, 2021
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Strategic Quality Solutions, LLC</b>
Contact	Adrienne Von Foller

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/k201426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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