

K223238 STARband 3DApr 20, 2023
182 days to decisionK223238 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k223238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Oct 20, 2022
Decision date	Apr 20, 2023
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthomerica Products, Inc.
Location	Washington, DC, US
Contact	David C Kerr
510(k) history	21 submissions · 21 cleared · 2000-2024

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