

K180568 KidCapOct 16, 2018
225 days to decisionK180568 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k180568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Mar 5, 2018
Decision date	Oct 16, 2018
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eastern Cranial Affiliates, LLC
Location	Fairfax, VA, US
Contact	Joseph Terpenning
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180568/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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