

K013458 CRANIAL HELMETOct 29, 2001
11 days to decisionK013458 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k013458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Oct 18, 2001
Decision date	Oct 29, 2001
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Children&apos;S Hospital
Location	Minneapolis, MN, US
Contact	CONNIE FICKLIN
510(k) history	1 submissions · 1 cleared · 2001-2001

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