

K003035 CLARREN HELMETJun 6, 2001
251 days to decisionK003035 · Product code: **MVA** · Neurology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Sep 28, 2000
Decision date	Jun 6, 2001
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Children&apos;S Hospital & Medical Center
Location	Washington, DC, US
Contact	DAVID J BLOCH
510(k) history	1 submissions · 1 cleared · 2001-2001

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