

**K021221 O&P CRANICAL MOLDING HELMET**Jul 1, 2002  
75 days to decisionK021221 · Product code: **MVA** · Neurology  
Source: <https://www.510kdatabase.net/k021221/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Apr 17, 2002
Decision date	Jul 1, 2002
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthotic &amp; Prosthetic Lab, Inc.</b>
Location	Webster Groves, MO, US
Contact	THOMAS MALONE
510(k) history	2 submissions · 2 cleared · 2002-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021221/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026