

**K063395 O&P BIVALVE CRANIAL MOLDING HELMET**Dec 22, 2006  
43 days to decisionK063395 · Product code: **MVA** · Neurology  
Source: <https://www.510kdatabase.net/k063395/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Nov 9, 2006
Decision date	Dec 22, 2006
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063395/> 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