

**K003630 DANMAR PRODUCTS MICHIGAN CRANIAL HELMET**May 29, 2001  
186 days to decisionK003630 · Product code: **MVA** · Neurology  
Source: <https://www.510kdatabase.net/k003630/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Nov 24, 2000
Decision date	May 29, 2001
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Danmar Products, Inc.</b>
Location	Ann Arbor, MI, US
Contact	KAREN A LINDNER
510(k) history	3 submissions · 3 cleared · 2001-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003630/> 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 21, 2026