

**K012920 MOLDED CRANIAL HELMET**Nov 28, 2001  
90 days to decisionK012920 · Product code: **MVA** · Neurology  
Source: <https://www.510kdatabase.net/k012920/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Aug 30, 2001
Decision date	Nov 28, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Fairview Orthopedic Laboratory</b>
Location	Minneapolis, MN, US
Contact	ROSS C D&apos;EMANUELE
510(k) history	1 submissions · 1 cleared · 2001-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012920/> 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 30, 2026