

K000861 CRANIOCAPOct 30, 2000
227 days to decisionK000861 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k000861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Mar 17, 2000
Decision date	Oct 30, 2000
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gillette Children's Specialty Healthcare
Location	Eagan, MN, US
Contact	LINDA VALERI
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000861/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026