

K011433 BALLERT CRANIAL MOLDING HELMETJun 12, 2001
33 days to decisionK011433 · Product code: **MVA** · Neurology
Source: <https://www.510kdatabase.net/k011433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	May 10, 2001
Decision date	Jun 12, 2001
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gema, Inc.
Location	Chicago, IL, US
Contact	GENE BERNARDONI
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011433/> 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