

K122353 CRAINFIX 2 TITANIUM CLAMP SYSTEMAug 30, 2012
27 days to decisionK122353 · Product code: **GXN** · Neurology
Source: <https://www.510kdatabase.net/k122353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Aug 3, 2012
Decision date	Aug 30, 2012
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap, Inc.
Location	Burlingame, CA, US
Contact	DENISE ADAMS
510(k) history	207 submissions · 201 cleared · 1991-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122353/> 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 13, 2026