FDA 510(k) Premarket Notification

K122353 CRAINFIX 2 TITANIUM CLAMP SYSTEM

CLEARED

Aug 30, 2012
27 days to decision

K122353 · 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