FDA 510(k) Premarket Notification

K111247 CRANIAL REMOLDING ORTHOSIS

CLEARED

Aug 15, 2011
104 days to decision

K111247 · Product code: **MVA** · Neurology
Source: https://www.510kdatabase.net/k111247/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	May 3, 2011
Decision date	Aug 15, 2011
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthotic Care Services, Llp**
Location	St.Paul, MN, US
Contact	SCOTT HINSHON
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k111247/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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