

K121304 OSTEOMED CRANIAL DISTRACTION SYSTEMAug 22, 2012
113 days to decisionK121304 · Product code: **PBJ** · Neurology
Source: <https://www.510kdatabase.net/k121304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Distraction System (PBJ)
Date received	May 1, 2012
Decision date	Aug 22, 2012
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed
Location	Addison, TX, US
Contact	PIEDAD PENA
510(k) history	12 submissions · 12 cleared · 2012-2021

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