

**K123885 OSTEOMED SMARTFLEX CRANIAL SPRING
DISTRACTOR**

Jun 3, 2013
167 days to decision

K123885 · Product code: **PBJ** · Neurology
Source: <https://www.510kdatabase.net/k123885/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Distraction System (PBJ)
Date received	Dec 18, 2012
Decision date	Jun 3, 2013
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed LP
Location	Addison, TX, US
Contact	PIEDAD PENA
510(k) history	29 submissions · 29 cleared · 2003-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k123885/> 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 May 17, 2026