

**K162542 OsteoMed PINNACLE Driver**May 19, 2017  
249 days to decisionK162542 · Product code: **HBE** · Neurology  
Source: <https://www.510kdatabase.net/k162542/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Sep 12, 2016
Decision date	May 19, 2017
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osteomed</b>
Location	Addison, TX, US
Contact	KATHRYN A. JAYNE
510(k) history	12 submissions · 12 cleared · 2012-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162542/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026