

**K130412 OSTEOMED EXTREMIFUSE SYSTEM**May 31, 2013  
101 days to decisionK130412 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k130412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 19, 2013
Decision date	May 31, 2013
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osteomed</b>
Location	Addison, TX, US
Contact	PIEDAD PENA
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/k130412/> 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