

**K111418 STAXX(R) XD SYSTEM**Dec 13, 2011  
207 days to decisionK111418 · Product code: **MQP** · Orthopedic  
Source: <https://www.510kdatabase.net/k111418/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	May 20, 2011
Decision date	Dec 13, 2011
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spine Wave, Inc.</b>
Location	Shelton, CT, US
Contact	ROAIDA RIZKALLAH
510(k) history	57 submissions · 57 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111418/> 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 18, 2026