

**K111294 SANTORINI SPINAL SYSTEM**Jan 27, 2012  
262 days to decisionK111294 · Product code: **MQP** · Orthopedic  
Source: <https://www.510kdatabase.net/k111294/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	May 10, 2011
Decision date	Jan 27, 2012
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>K2m, Inc.</b>
Location	Leesburg, VA, US
Contact	NANCY GIEZEN
510(k) history	100 submissions · 97 cleared · 2007-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111294/> 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