

**K160982 Sphynx™**Dec 22, 2016  
259 days to decisionK160982 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k160982/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 7, 2016
Decision date	Dec 22, 2016
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eden Spine, LLC</b>
Location	Apple Valley, MN, US
Contact	Guillaume Viallaneix
510(k) history	2 submissions · 2 cleared · 2012-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160982/> 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 16, 2026