

**K112607 SPINEVISION LUMIS(TM) CANNULATED POLYAXIAL  
PEDICLE SCREW FIXATION SYSTEM, SPINEVISION U.L.I.S.(TM)  
POLYAXIAL PEDICLE ...**Jun 7, 2012  
274 days to decisionK112607 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k112607/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 7, 2011
Decision date	Jun 7, 2012
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinevision S.A.</b>
Location	Douglassville, PA, US
Contact	DONALD W GUTHNER
510(k) history	5 submissions · 5 cleared · 2012-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112607/> 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 17, 2026