

**K130302 SPINEVISION LUMIS CANNULATED POLYAXIAL  
 PEDICLE SCREW FIXATION SYSTEM, SPINEVISION U.L.I.S.  
 POLYAXIAL PEDICLE SCREW FIXAT**

Jul 30, 2013  
 173 days to decision

K130302 · Product code: **MNI** · Orthopedic  
 Source: <https://www.510kdatabase.net/k130302/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 7, 2013
Decision date	Jul 30, 2013
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinevision S.A.</b>
Location	Douglassville, PA, US
Contact	HELENE PLAS
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/k130302/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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