

**K111883 SMARTLOC SPINAL FIXATION SYSTEM**Oct 18, 2011  
109 days to decisionK111883 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k111883/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 1, 2011
Decision date	Oct 18, 2011
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>A-Spine Asia, Co., Ltd.</b>
Location	Taipei, Neihu District, TW
Contact	FRANK HSU
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111883/> 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