

**K101374 AAXTER A3 POSTERIOR SPINAL SYSTEM**Mar 16, 2011  
303 days to decisionK101374 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k101374/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	May 17, 2010
Decision date	Mar 16, 2011
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aaxter Co., Ltd.</b>
Location	Taipei, TW
Contact	JACK CHEN
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/k101374/> 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