

**K130825 AZURE ANTERIOR CERVICAL PLATE SYSTEM**May 7, 2013  
42 days to decisionK130825 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k130825/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 26, 2013
Decision date	May 7, 2013
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix, Inc.</b>
Location	Mckinney, TX, US
Contact	ALLY BADUEL
510(k) history	57 submissions · 57 cleared · 1996-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130825/> 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 15, 2026