

**K162638 CETRA Anterior Cervical Plate System**Dec 16, 2016  
85 days to decisionK162638 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k162638/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 22, 2016
Decision date	Dec 16, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix, Inc.</b>
Location	Mckinney, TX, US
Contact	Jacki Koch
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/k162638/> 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