

**K163602 Kepler I Cervical Plate System**Feb 16, 2017  
57 days to decisionK163602 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k163602/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 21, 2016
Decision date	Feb 16, 2017
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orbbo Surgical, LLC</b>
Location	Los Angeles, CA, US
Contact	Eric Garofano
510(k) history	4 submissions · 4 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163602/> 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 16, 2026