

**K163265 Kepler II**Apr 7, 2017  
137 days to decisionK163265 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k163265/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 21, 2016
Decision date	Apr 7, 2017
Days to decision	137 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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