

**K122872 INTERVERTEBRAL BODY FUSION DEVICE**Feb 28, 2013  
162 days to decisionK122872 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k122872/>**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	Sep 19, 2012
Decision date	Feb 28, 2013
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dio Medical Co., Ltd.</b>
Location	Santa Fe Springs, CA, US
Contact	APRIL LEE
510(k) history	7 submissions · 7 cleared · 2010-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122872/> 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