

**K153237 OrthAlign Plus System**Mar 1, 2016  
113 days to decisionK153237 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k153237/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 9, 2015
Decision date	Mar 1, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthalign, Inc.</b>
Location	Newport Beach, CA, US
Contact	David Vancelette
510(k) history	13 submissions · 13 cleared · 2009-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153237/> 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 26, 2026