

**K253507 Packaged Assembly, Reusable Navigation Unit**Jun 2, 2026  
211 days to decisionK253507 · Product code: **ONN** · Orthopedic  
Source: <https://www.510kdatabase.net/k253507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoperative Orthopedic Joint Assessment Aid (ONN)
Date received	Nov 3, 2025
Decision date	Jun 2, 2026
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Lantern ASC, Smart Pack kit, Knee

**APPLICANT**

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Company	<b>Orthalign, Inc.</b>
Location	Newport Beach, CA, US
Contact	Michaela Lindemann
510(k) history	14 submissions · 14 cleared · 2009-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253507/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 27, 2026