

**K180523 INTAI Surgery Navigation System**Sep 20, 2019  
570 days to decisionK180523 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k180523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Feb 27, 2018
Decision date	Sep 20, 2019
Days to decision	570 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intai Technology Corporation</b>
Location	Taichung, TW
Contact	Shih-Chang Chuang
510(k) history	2 submissions · 2 cleared · 2019-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180523/> 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 27, 2026