

**K214059 CoreLink Navigation Instruments**Jan 19, 2022  
23 days to decisionK214059 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k214059/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 27, 2021
Decision date	Jan 19, 2022
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Corelink, LLC</b>
Location	Round Rock, TX, US
Contact	Steven Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Empirical Testing Corp</b>
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214059/> 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 May 13, 2026