

**K232116 CoreLink Navigation Instruments**Aug 16, 2023  
30 days to decisionK232116 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k232116/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received         | Jul 17, 2023                            |
| Decision date         | Aug 16, 2023                            |
| Days to decision      | 30 days                                 |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------|
| Consulting firm | <b>Empirical Technologies</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)

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