

K172115 Navigated Instrument SystemMar 8, 2018
238 days to decisionK172115 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k172115/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Jul 13, 2017 |
| Decision date | Mar 8, 2018 |
| Days to decision | 238 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Orthofix, Inc. |
| Location | Mckinney, TX, US |
| Contact | Jacki Koch |
| 510(k) history | 57 submissions · 57 cleared · 1996-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172115/> Data sourced from FDA 510(k) public records (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. - Generated May 15, 2026