

K202836 GX Navigation Instrument SystemAug 19, 2021
328 days to decisionK202836 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k202836/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Sep 25, 2020 |
| Decision date | Aug 19, 2021 |
| Days to decision | 328 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Life Spine, Inc. |
| Location | Hoffman Estates, IL, US |
| Contact | Angela Batker |
| 510(k) history | 82 submissions · 82 cleared · 2011-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202836/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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