

K231527 TriALTIS Navigation Enabled InstrumentsSep 29, 2023
126 days to decisionK231527 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k231527/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | May 26, 2023 |
| Decision date | Sep 29, 2023 |
| Days to decision | 126 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medos International S?rl |
| Location | Lelocle, CH |
| Contact | Nicole Aeschbacher |
| 510(k) history | 4 submissions · 4 cleared · 2016-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------|
| Consulting firm | Synthes GmbH |
| Contact | Nicole Aeschbacher |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231527/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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