

K181449 Ortoma Treatment Solution - OTSSep 19, 2018
110 days to decisionK181449 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k181449/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Jun 1, 2018 |
| Decision date | Sep 19, 2018 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ortoma AB |
| Location | Goteborg, SE |
| Contact | Linus Bystrom |
| 510(k) history | 3 submissions · 3 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181449/> 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 27, 2026