

K182964 ROSA Knee SystemJan 24, 2019
91 days to decisionK182964 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k182964/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Oct 25, 2018 |
| Decision date | Jan 24, 2019 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Orthosoft Inc. (d/b/a) Zimmer CAS |
| Location | Montreal, CA |
| Contact | Eric DesRosiers |
| Website | https://www.zimmerbiomet.com |
| 510(k) history | 18 submissions · 18 cleared · 2017-2026 |

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