

K213380 360CASJan 11, 2022
90 days to decisionK213380 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k213380/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Oct 13, 2021 |
| Decision date | Jan 11, 2022 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Kico Knee Innovation Company Pty Limited |
| Location | Pymble, AU |
| Contact | Stefanie Auf Der Mauer |
| 510(k) history | 4 submissions · 4 cleared · 2017-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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