

K192495 Black Diamond Navigation InstrumentsJan 17, 2020
128 days to decisionK192495 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k192495/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthopedic Stereotaxic Instrument (OLO) |
| Date received | Sep 11, 2019 |
| Decision date | Jan 17, 2020 |
| Days to decision | 128 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Osseus Fusion Systems |
| Location | Dallas, TX, US |
| Contact | Robert Pace |
| 510(k) history | 5 submissions · 5 cleared · 2019-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192495/> 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 26, 2026