

K233375 Tranquil-L Interbody SystemMar 20, 2024
170 days to decisionK233375 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k233375/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Oct 2, 2023 |
| Decision date | Mar 20, 2024 |
| Days to decision | 170 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nexus Spine, LLC |
| Location | Salt Lake City, UT, US |
| Contact | Jared Crocker |
| Website | https://nexusspine.com |
| 510(k) history | 17 submissions · 17 cleared · 2014-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------|
| Consulting firm | MRC Global |
| Contact | Christine Scifert |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233375/>; 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 14, 2026