

K253538 TeKBrace Knotless AnchorMar 6, 2026
113 days to decisionK253538 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k253538/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Nov 13, 2025 |
| Decision date | Mar 6, 2026 |
| Days to decision | 113 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Theramicro |
| Location | Cordova, TN, US |
| Contact | Christine Scifert |
| 510(k) history | 2 submissions · 2 cleared · 2025-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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