

K221135 X-Twist PEEK Suture AnchorMay 19, 2022
30 days to decisionK221135 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k221135/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Apr 19, 2022 |
| Decision date | May 19, 2022 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Parcus Medical, LLC |
| Location | Sturgeon Bay, WI, US |
| Contact | Calen Souther |
| 510(k) history | 28 submissions · 28 cleared · 2009-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221135/> 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