

K172186 BioWick X Implant with DriverOct 16, 2017
88 days to decisionK172186 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k172186/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Jul 20, 2017 |
| Decision date | Oct 16, 2017 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Cayenne Medical, Inc. |
| Location | San Diego, CA, US |
| Contact | Shima Hashemian |
| 510(k) history | 22 submissions · 22 cleared · 2006-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172186/> 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