

K170571 Tyber Medical BioTy(TM) Nanotopography Trauma Screw, TyFix ScrewJun 20, 2017
113 days to decisionK170571 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k170571/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Feb 27, 2017 |
| Decision date | Jun 20, 2017 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tyber Medical, LLC |
| Location | Morristown, NJ, US |
| Contact | Mark F. Schenk |
| Website | https://www.tybermed.com |
| 510(k) history | 28 submissions · 28 cleared · 2013-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170571/> 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 16, 2026