

K173556 Injection ScrewJul 13, 2018
238 days to decisionK173556 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k173556/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Nov 17, 2017 |
| Decision date | Jul 13, 2018 |
| Days to decision | 238 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biedermann Medtech, Inc. |
| Location | Miami, FL, US |
| Contact | Michelle Montesino |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173556/> 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