

K191771 SECURE ScrewOct 16, 2019
106 days to decisionK191771 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k191771/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Jul 2, 2019 |
| Decision date | Oct 16, 2019 |
| Days to decision | 106 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | A.M. Surgical, Inc. |
| Location | Great Neck, NY, US |
| Contact | Vincent Pascale |
| 510(k) history | 6 submissions · 6 cleared · 1998-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191771/> 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 June 25, 2026