

K971069 TWIST-OFF (TM) SCREWJul 9, 1997
107 days to decisionK971069 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k971069/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Mar 24, 1997 |
| Decision date | Jul 9, 1997 |
| Days to decision | 107 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Landos, Inc. |
| Location | Malvern, PA, US |
| Contact | KATH LAFFAN |
| 510(k) history | 15 submissions · 12 cleared · 1994-1997 |

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