

K124027 MONSTER SCREW SYSTEMApr 5, 2013
98 days to decisionK124027 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k124027/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Dec 28, 2012 |
| Decision date | Apr 5, 2013 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Apogee Orthosolutions |
| Location | Chesterland, OH, US |
| Contact | KAREN E WARDEN, PHD |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k124027/> 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 18, 2026