

K102601 ORTHOFLEX RODJan 14, 2011
127 days to decisionK102601 · Product code: **KWH** · Orthopedic
Source: <https://www.510kdatabase.net/k102601/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Toe, Constrained, Polymer (KWH) |
| Date received | Sep 9, 2010 |
| Decision date | Jan 14, 2011 |
| Days to decision | 127 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ortho-Pro, LLC |
| Location | Round Rock, TX, US |
| Contact | J.D. WEBB |
| 510(k) history | 4 submissions · 4 cleared · 2003-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102601/> 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