

K152295 Talon DistalFix Antegrade/Retrograde Femoral NailNov 3, 2015
82 days to decisionK152295 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k152295/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Aug 13, 2015 |
| Decision date | Nov 3, 2015 |
| Days to decision | 82 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Orthopedic Designs North America, Inc. |
| Location | Tampa, FL, US |
| Contact | Robin Wilson |
| 510(k) history | 4 submissions · 4 cleared · 2011-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152295/> 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 27, 2026