

K180730 INVISION Total Ankle Revision SystemJul 11, 2018
113 days to decisionK180730 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k180730/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN) |
| Date received | Mar 20, 2018 |
| Decision date | Jul 11, 2018 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Wrightmedicaltechnologyinc |
| Location | Arlington, TN, US |
| Contact | Alayne Melancon |
| 510(k) history | 302 submissions · 291 cleared · 1993-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180730/> 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 16, 2026