

K053569 AGILITY LP TOTAL ANKLE PROSTHESISMar 31, 2006
99 days to decisionK053569 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k053569/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN) |
| Date received | Dec 22, 2005 |
| Decision date | Mar 31, 2006 |
| Days to decision | 99 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | DePuy Orthopaedics, Inc. |
| Location | Warsaw, IN, US |
| Contact | NATALIE S HECK |
| 510(k) history | 206 submissions · 204 cleared · 1998-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053569/> 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 26, 2026