

**K013430 ACE BIO WIN TIBIAL NAILING SYSTEM**Dec 17, 2001  
62 days to decisionK013430 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k013430/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Oct 16, 2001
Decision date	Dec 17, 2001
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>DePuy Orthopaedics, Inc.</b>
Location	Warsaw, IN, US
Contact	MARCIA J ARENTZ
510(k) history	206 submissions · 204 cleared · 1998-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013430/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026