

**K992350 PYLON INTRAMEDULLARY NAIL SYSTEM**Sep 22, 1999  
70 days to decisionK992350 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k992350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jul 14, 1999
Decision date	Sep 22, 1999
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alphatec Mfg., Inc.</b>
Location	Palm Desert, CA, US
Contact	JASON BLAIN
510(k) history	20 submissions · 18 cleared · 1990-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992350/> 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 20, 2026