

**K961608 SYNTHES (U.S.A.) POLYPIN**May 9, 1997  
379 days to decisionK961608 · Product code: HTY · Orthopedic  
Source: <https://www.510kdatabase.net/k961608/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Apr 25, 1996
Decision date	May 9, 1997
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Synthes (Usa)</b>
Location	Mchenry, IL, US
Contact	ANGELA J SILVESTRI
510(k) history	411 submissions · 394 cleared · 1977-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961608/> 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 14, 2026