

**K112689 SYNTHES STERNAL FIXATION SYSTEM**Oct 26, 2011  
41 days to decisionK112689 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k112689/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 15, 2011
Decision date	Oct 26, 2011
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes, Inc.</b>
Location	19380, PA, US
Contact	ELIZABETH KIERZEK
510(k) history	8 submissions · 8 cleared · 2011-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112689/> 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 18, 2026