

**K181296 Syntec Femoral Nail System**Apr 11, 2019  
330 days to decisionK181296 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k181296/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 16, 2018
Decision date	Apr 11, 2019
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syntec Scientific Corporation</b>
Location	Chang Hua, TW
Contact	Nicole Tseng
510(k) history	6 submissions · 6 cleared · 2017-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181296/> 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