

K161327 SYNTEC HUMERAL NAIL SYSTEMJun 8, 2017
392 days to decisionK161327 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k161327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 12, 2016
Decision date	Jun 8, 2017
Days to decision	392 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syntec Scientific Corporation
Location	Chang Hua, TW
Contact	KAVIN CHU
510(k) history	6 submissions · 6 cleared · 2017-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161327/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026