

K111891 SYNTHES BRAINLAB TRAUMA COMPATIBLE INSTRUMENTSNov 28, 2011
146 days to decisionK111891 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k111891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jul 5, 2011
Decision date	Nov 28, 2011
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	CHRISTOPHER HACK
510(k) history	60 submissions · 60 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111891/> 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 18, 2026