

K163589 SIGN IM NailJul 20, 2017
212 days to decisionK163589 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k163589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Dec 20, 2016
Decision date	Jul 20, 2017
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sign Fracture Care International
Location	Richland, WA, US
Contact	Robert Schmitt
510(k) history	4 submissions · 4 cleared · 2013-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163589/> 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 16, 2026