

K163368 FITBONE TAAJan 26, 2017
57 days to decisionK163368 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k163368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Nov 30, 2016
Decision date	Jan 26, 2017
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wittenstein Intens GmbH
Location	Igersheim, DE
Contact	Hartmut Kampa
510(k) history	2 submissions · 2 cleared · 2017-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163368/> 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 27, 2026