

K203399 FITBONE(R) TAAFeb 17, 2021
90 days to decisionK203399 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k203399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Nov 19, 2020
Decision date	Feb 17, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Wagoner Consulting Llg
Contact	Cheryl Wagoner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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