

K180436 T2 Alpha Tibia Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System, IMN Screws System, IMN Instruments SystemJun 6, 2018
106 days to decisionK180436 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k180436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 20, 2018
Decision date	Jun 6, 2018
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Trauma GmbH
Location	Mahwah, NJ, US
Contact	Heike Gustke
510(k) history	7 submissions · 7 cleared · 2015-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180436/> 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 15, 2026