

**K250163 T2 Alpha Femur Retrograde Nailing System**Aug 13, 2025  
204 days to decisionK250163 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k250163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jan 21, 2025
Decision date	Aug 13, 2025
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker GmbH</b>
Location	Selzach, Solothurn, Ch, CH
Contact	Ileana Freige
Website	<a href="https://www.stryker.com">https://www.stryker.com</a>
510(k) history	54 submissions · 54 cleared · 2015-2026

Stryker GmbH is a medical device manufacturer based in Selzach, Solothurn, Switzerland. The company specializes in orthopedic surgical devices and implants. Stryker GmbH has received FDA 510(k) clearances from total submissions since 2015. The company's regulatory portfolio is entirely focused on orthopedic devices, reflecting its core expertise in fracture fixation and surgical instrumentation. The latest clearance was granted in 2026, demonstrating continued active development and market engagement. Recent cleared devices include femur and humerus nailing systems, dista...