

**K251400 T2 Alpha Humerus Nailing System**Aug 20, 2025  
106 days to decisionK251400 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k251400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 6, 2025
Decision date	Aug 20, 2025
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	IMN Screws System; T2 Nailing System

**APPLICANT**

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Company	<b>Stryker GmbH</b>
Location	Selzach, Solothurn, Ch, CH
Contact	Jackie Perri
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...