

K253640 T2 Alpha Femur Retrograde Nailing SystemFeb 3, 2026
76 days to decisionK253640 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k253640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Nov 19, 2025
Decision date	Feb 3, 2026
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pangea Femur Reconstruction System

APPLICANT

Company	Stryker GmbH
Location	Selzach, Solothurn, Ch, CH
Contact	Ileana Freige
Website	https://www.stryker.com
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...