

**K222309 Gamma4 System**Nov 15, 2022  
106 days to decisionK222309 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k222309/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Aug 1, 2022
Decision date	Nov 15, 2022
Days to decision	106 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	Cindy Leon
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...