

K213328 Gamma4 System, Gamma3 System, IMN Screws System, T2 Tibial Nailing System

Feb 11, 2022
129 days to decision

K213328 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k213328/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Oct 5, 2021
Decision date	Feb 11, 2022
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker GmbH
Location	Selzach, Solothurn, Ch, CH
Contact	Cindy Leon
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...