

K200880 T2 Tibial Nailing System, T2 Femoral Nail System, T2 Supracondylar Nail System, T2 Recon Nail System, T2 Greater Trochanter Nail (GTN),T2 Ankle Arthrodesis Nail,T2 Arthrodesis Nail System

Jul 1, 2020
90 days to decision

K200880 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k200880/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 2, 2020
Decision date	Jul 1, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker GmbH
Location	Selzach, Solothurn, Ch, CH
Contact	Jackie Perri
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...