

K151879 VariAx 2 One-Third Tubular Plating SystemAug 6, 2015
28 days to decisionK151879 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k151879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 9, 2015
Decision date	Aug 6, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker GmbH
Location	Selzach, Solothurn, Ch, CH
Contact	HEIKE GUSTKE
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...
