

**K162841 VariAx Distal Radius Plating System, VariAx 2 System**Feb 21, 2017  
133 days to decisionK162841 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k162841/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 11, 2016
Decision date	Feb 21, 2017
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker GmbH</b>
Location	Selzach, Solothurn, Ch, CH
Contact	Irene Bacalocostantis
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...

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