

**K191412 VariAx 2 System, VariAx 2 Mini Fragment System**Aug 23, 2019  
87 days to decisionK191412 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k191412/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 28, 2019
Decision date	Aug 23, 2019
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker GmbH</b>
Location	Selzach, Solothurn, Ch, CH
Contact	Sanja Jahr
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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