

**K242445 Pangea Platform**Oct 6, 2024  
51 days to decisionK242445 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k242445/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Plate, Fixation, Bone (HRS)   |
| Date received         | Aug 16, 2024  |
| Decision date         | Oct 6, 2024   |
| Days to decision      | 51 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |
| Other names           | Pangea Femur Plating System; Pangea Humerus Plating System; Pangea Tibia Plating System |

**APPLICANT**

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|----------------|---|
| Company        | <b>Stryker GmbH</b>   |
| Location       | Selzach, Solothurn, Ch, CH                                    |
| Contact        | Ashley Allison  |
| 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...