

K153379 AxSOS 3TiMay 26, 2016
185 days to decisionK153379 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k153379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 23, 2015
Decision date	May 26, 2016
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker GmbH
Location	Selzach, Solothurn, Ch, CH
Contact	Saad Attiyah
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...
