

K151178 VariAx 2 Wrist Fusion SystemJun 24, 2015
51 days to decisionK151178 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k151178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 4, 2015
Decision date	Jun 24, 2015
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Trauma AG
Location	Malwah, NJ, US
Contact	DR. HEIKE GUSTKE
510(k) history	25 submissions · 25 cleared · 2013-2017

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