

**K233994 VOLT™ Proximal Humerus 3.5 Plating System**Jul 26, 2024  
221 days to decisionK233994 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k233994/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 18, 2023
Decision date	Jul 26, 2024
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes GmbH</b>
Location	Zuchwil, CH
Contact	Brendan Daly
510(k) history	7 submissions · 7 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233994/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026