

K254054 VOLT™ Ankle Trauma 2.7/3.5 Plating SystemMar 2, 2026
75 days to decisionK254054 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k254054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 17, 2025
Decision date	Mar 2, 2026
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VOLT™ Calcaneus 2.7 Plating System

APPLICANT

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

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