

K234062 APTUS Hand Scaphoid PlatesMar 21, 2024
90 days to decisionK234062 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k234062/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 22, 2023
Decision date	Mar 21, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medartis AG
Location	San Diego, CA, US
Contact	Claudia De Santis
510(k) history	41 submissions · 41 cleared · 1999-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234062/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026