

K230971 APTUS® 3.5 TriLock Straight PlatesJun 2, 2023
58 days to decisionK230971 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k230971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 5, 2023
Decision date	Jun 2, 2023
Days to decision	58 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

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin A. Thomas, PhD

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230971/> 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