

**K253916 APTUS Shoulder Proximal Humerus System,
PentaLock 3.5**

Mar 16, 2026
98 days to decision

K253916 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k253916/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 8, 2025
Decision date	Mar 16, 2026
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253916/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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