

**K232144 Sterile Products of the APTUS System**Aug 18, 2023  
30 days to decisionK232144 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k232144/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 19, 2023
Decision date	Aug 18, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medartis, Inc.</b>
Contact	Chelsea Kozior

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232144/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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