

**K193639 APTUS® Foot 2.8-3.5 System**Mar 26, 2020  
90 days to decisionK193639 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k193639/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 27, 2019
Decision date	Mar 26, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193639/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 15, 2026