

K193633 APTUS® Ankle Trauma System 2.8/3.5Mar 26, 2020
90 days to decisionK193633 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k193633/>**SUBMISSION DETAILS**

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

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

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