

K202589 APTUS Cannulated Compression Screws, APTUS headed Cannulated Compression Screws, APTUS K-Wire SystemNov 6, 2020
59 days to decisionK202589 · Product code: **HWC** · General Hospital
Source: <https://www.510kdatabase.net/k202589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 8, 2020
Decision date	Nov 6, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medartis AG
Location	San Diego, CA, US
Contact	Andrea Kiefer-Schweizer
510(k) history	42 submissions · 42 cleared · 1999-2026

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Lauren M. Wessell

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

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