

K161861 APTUS® Coronoid 2.0Feb 9, 2017
218 days to decisionK161861 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k161861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 6, 2016
Decision date	Feb 9, 2017
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161861/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026