

K220362 LE-12CHMar 25, 2022
45 days to decisionK220362 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k220362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Feb 8, 2022
Decision date	Mar 25, 2022
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Caf Medical Solutions, Inc.
Location	Hockley, TX, US
Contact	Oscar Arriaga Yamin
510(k) history	3 submissions · 3 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Compliance4Devices
Contact	Juan Tezak

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220362/> 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 27, 2026