

K212163 Coala Heart MonitorApr 14, 2022
276 days to decisionK212163 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k212163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 12, 2021
Decision date	Apr 14, 2022
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coala Life AB
Location	Stockholm, SE
Contact	Dan Pitulia
510(k) history	2 submissions · 2 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies
Contact	Pierre Bounaud

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/k212163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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