

K221260 CSF-3Jan 6, 2023
249 days to decisionK221260 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k221260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 2, 2022
Decision date	Jan 6, 2023
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiacsense
Location	Caesarea, IL
Contact	Benita Lanzer
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Oxana S. Pantchenko

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT05322382****Accuracy of Pulse Oximeters With Profound Hypoxia**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	12 patients (actual)
Study sites	1 site
Condition studied	SpO2
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 3, 2021
Sponsor	CardiacSense Ltd. (Industry)

Primary outcome**Accuracy of pulse oximeter with profound hypoxia**Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05322382