

K250922 Edema Guard Monitor (EGM) CardioSet-001Sep 9, 2025
166 days to decisionK250922 · Product code: **DSB** · Cardiovascular
Source: <https://www.510kdatabase.net/k250922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Mar 27, 2025
Decision date	Sep 9, 2025
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardioset Medical , Ltd.
Location	Matan, IL
Contact	Assaf Gur
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells Llp
Contact	John Smith

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/k250922/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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