

K222330 The Heart SeatApr 24, 2023
265 days to decisionK222330 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k222330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Aug 2, 2022
Decision date	Apr 24, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Casana Care, Inc.
Location	Rochester, NY, US
Contact	Kara Johnson
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting
Contact	Donna-Bea Tillman

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

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