

K233864 ASSURE Wearable ECGMay 7, 2024
153 days to decisionK233864 · Product code: **MWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k233864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Dec 6, 2023
Decision date	May 7, 2024
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kestra Medical Technologies, Inc.
Location	Kirkland, WA, US
Contact	Beverly Magrane
510(k) history	1 submissions · 1 cleared · 2024-2024

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