

K210758 Q PatchJun 2, 2022
444 days to decisionK210758 · Product code: **MWJ** · CardiovascularSource: <https://www.510kdatabase.net/k210758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Mar 15, 2021
Decision date	Jun 2, 2022
Days to decision	444 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medicalgorithmics S.A.
Location	New York, NY, US
Contact	Maciej Gamrot
510(k) history	11 submissions · 11 cleared · 2012-2025

REGULATORY CONSULTANT

Consulting firm	Medicalgorithmics US Holding Corporation
Contact	Agnieszka Romowicz

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/k210758/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026