FDA 510(k) Premarket Notification

K210160 AlertWatch:AC

CLEARED

Sep 10, 2021
232 days to decision

K210160 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k210160/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Jan 21, 2021
Decision date	Sep 10, 2021
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alertwatch, Inc.**
Location	Ann Arbor, MI, US
Contact	Justin Adams
510(k) history	2 submissions · 2 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	**Biologics Consulting Group, Inc.**
Contact	Donna-Bea Tillman

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210160/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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