

K153335 AlertWatch: ORMar 15, 2016
117 days to decisionK153335 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k153335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Nov 19, 2015
Decision date	Mar 15, 2016
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alertwatch, LLC
Location	Clarksville, MD, US
Contact	Justin Adams
510(k) history	2 submissions · 2 cleared · 2014-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153335/> 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 June 3, 2026