FDA 510(k) Premarket Notification

K153335 AlertWatch: OR

CLEARED

Mar 15, 2016
117 days to decision

K153335 · 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