

K143751 Visi Mobile Monitoring SystemJan 23, 2015
23 days to decisionK143751 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k143751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 31, 2014
Decision date	Jan 23, 2015
Days to decision	23 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Sotera Wireless, Inc.
Location	San Diego, CA, US
Contact	Eben Gordon
510(k) history	9 submissions · 9 cleared · 2012-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143751/> 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 30, 2026