

**K130709 VISI MOBILE MONITORING SYSTEM**Oct 7, 2013  
206 days to decisionK130709 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130709/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Mar 15, 2013
Decision date	Oct 7, 2013
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sotera Wireless, Inc.</b>
Location	San Diego, CA, US
Contact	EBEN GORDON
510(k) history	9 submissions · 9 cleared · 2012-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130709/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026