

**K132229 OMNI PATENT MONITORS**Feb 21, 2014  
218 days to decisionK132229 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k132229/>**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	Jul 18, 2013
Decision date	Feb 21, 2014
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infinium Medical</b>
Location	Appollo Beach, FL, US
Contact	JOHN O'&BRIEN
510(k) history	6 submissions · 6 cleared · 2010-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132229/> 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 June 5, 2026