

K112329 OMNI PATIENT MONITORSep 8, 2011
27 days to decisionK112329 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k112329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Aug 12, 2011
Decision date	Sep 8, 2011
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infinium Medical
Location	Appollo Beach, FL, US
Contact	JOHN O'BRLEN
510(k) history	6 submissions · 6 cleared · 2010-2015

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