

K103268 OMNI EXPRESSNov 23, 2010
19 days to decisionK103268 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k103268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Nov 4, 2010
Decision date	Nov 23, 2010
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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