

K103737 OMNI II PATIENT MONITORJun 2, 2011
162 days to decisionK103737 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k103737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 22, 2010
Decision date	Jun 2, 2011
Days to decision	162 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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