FDA 510(k) Premarket Notification

K101052 OMNI III PATIENT MONITOR

CLEARED

Aug 11, 2010
118 days to decision

K101052 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k101052/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 15, 2010
Decision date	Aug 11, 2010
Days to decision	118 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