

K113835 DATACTOR SYSTEMJun 27, 2012
183 days to decisionK113835 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k113835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 27, 2011
Decision date	Jun 27, 2012
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Capsule Tech, Inc.
Location	Andover, MA, US
Contact	PETER KELLEY
510(k) history	1 submissions · 1 cleared · 2012-2012

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