

K152330 Expression MR400 MRI Patient Monitoring SystemDec 23, 2015
127 days to decisionK152330 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k152330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Aug 18, 2015
Decision date	Dec 23, 2015
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Invivo Corporation
Location	Pewaukee, WI, US
Contact	Rusty Kelly
510(k) history	29 submissions · 29 cleared · 2005-2021

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