FDA 510(k) Premarket Notification

K103700 ESSENTIAL MRI PATIENT MONITOR

CLEARED

Mar 15, 2011
85 days to decision

K103700 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k103700/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Dec 20, 2010
Decision date	Mar 15, 2011
Days to decision	85 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