FDA 510(k) Premarket Notification

K121860 ESA615

CLEARED

Jan 25, 2013
213 days to decision

K121860 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k121860/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jun 26, 2012
Decision date	Jan 25, 2013
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fluke Biomedical**
Location	Orange, CA, US
Contact	JOHN NELSON
510(k) history	6 submissions · 6 cleared · 2008-2013