

K110429 PROSIM 4, PROSIM 6, PROSIM 8Sep 2, 2011
199 days to decisionK110429 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k110429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Feb 15, 2011
Decision date	Sep 2, 2011
Days to decision	199 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

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