

**K121860 ESA615**Jan 25, 2013  
213 days to decisionK121860 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k121860/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121860/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 9, 2026