

**K091985 UNIVERSAL PHYSIOLOGICAL MEASUREMENT  
MODULE**Jul 24, 2009  
22 days to decisionK091985 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k091985/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 2, 2009
Decision date	Jul 24, 2009
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ivy Biomedical Systems, Inc.</b>
Location	Branford, CT, US
Contact	DICK LISTRO
Website	<a href="https://ivybiomedical.com">https://ivybiomedical.com</a>
510(k) history	27 submissions · 27 cleared · 1986-2024

Ivy Biomedical Systems, Inc. is a privately-held medical device company headquartered in Branford, Connecticut. The company is the market leader for precision cardiac gating monitors used for synchronization of radiographic image acquisition across major imaging modalities including nuclear medicine, computed tomography, magnetic resonance, positron emission tomography, and single photon emission computed tomography. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1986. Cardiovascular devices represent the dominant focus,...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k091985/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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