

**K884455 MODEL 702 ECG/RESPIRATION/TEMPERATURE**Mar 9, 1989  
136 days to decisionK884455 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k884455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Oct 24, 1988
Decision date	Mar 9, 1989
Days to decision	136 days
Third-party review	No

**APPLICANT**

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Company	<b>Ivy Biomedical Systems, Inc.</b>
Location	Branford, CT, US
Contact	BRENDA E LUNDY
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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