

**K023616 PHYSIOLOGICAL MONITOR, MODEL 3000 (SERIES)**Nov 4, 2002  
6 days to decisionK023616 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k023616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Oct 29, 2002
Decision date	Nov 4, 2002
Days to decision	6 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,...