

**K982255 MODEL 2000 PULSE OXIMETER**Oct 22, 1998  
118 days to decisionK982255 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k982255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 26, 1998
Decision date	Oct 22, 1998
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**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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