

K091787 MODEL 6000 TWO PARAMETER BEDSIDE MONITOROct 9, 2009
114 days to decisionK091787 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k091787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 17, 2009
Decision date	Oct 9, 2009
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ivy Biomedical Systems, Inc.
Location	Branford, CT, US
Contact	JENNIFER LAINE
Website	https://ivybiomedical.com
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,...
