

K901504 MODELS 706 ECG/PRESSURE/RESP./SAO2, 705 ECG/RESP.Aug 23, 1990
147 days to decisionK901504 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k901504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Mar 29, 1990
Decision date	Aug 23, 1990
Days to decision	147 days
Third-party review	No

APPLICANT

Company	Ivy Biomedical Systems, Inc.
Location	Branford, CT, US
Contact	STEVEN M SIMON
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,...

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