

**K862647 PHYSIOLOGICAL MONITOR, MODELS 401,402 & 403**Aug 18, 1986  
38 days to decisionK862647 · Product code: **DSK** · CardiovascularSource: <https://www.510kdatabase.net/k862647/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Blood-pressure (DSK)
Date received	Jul 11, 1986
Decision date	Aug 18, 1986
Days to decision	38 days
Third-party review	No

**APPLICANT**

---

Company	<b>Ivy Biomedical Systems, Inc.</b>
Location	Branford, CT, US
Contact	RICHARD A MENTELOS
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,...

---